

**EPA REGISTRATION NUMBER**  
**92334-1**

# PROCESSING REQUEST

Reg # 92334-1

Decision # 516525

Description: BASIC CSF APRIL 19, 2016

Electronic Label & Letter  
(see PPLS):

OR

Non Electronic  
Label & Letter  
(Scanning required):

☐ Dated:

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie Breeden-Alemi

Division: RD/IVB 1

Phone: 703-347-0511

Date: 2/1/17



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

92334-1

Date of Issuance:

2/2/17

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited  
Expires: 2/2/19

Name of Pesticide Product:

Evergreen II Spot On for Dogs

Name and Address of Registrant (include ZIP Code):

Robert Scharf, Managing Director  
Evergreen Animal health, LLC  
22655 Centennial Road  
Gretna, NE 68028

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03  
Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

2/2/17

2. This registration is time-limited and expires 2/2/19.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: internet, store, veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred (mm/dd/yyyy)
  - State in which the incident occurred (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)
  - Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other
  - Major signs noted with separate column for each sign, using standard terminology
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
  - a. Imidacloprid GDCI-129099-951
  - b. Permethrin GDCI-109701-1252
  - c. Pyriproxyfen GDCI-129032-1299
  - d. Pyriproxyfen EDSP-129032-187

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:  
[http://iaspub.epa.gov/apex/pesticides/f?p\\_chemicalsearch:1](http://iaspub.epa.gov/apex/pesticides/f?p_chemicalsearch:1)

6. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
7. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 92334-1."
8. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 04/19/2016

If you have any questions, you may contact Julie Breeden-Alemi at 703-347-0511 or via email at [Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov).

Enclosure

**[Front Panel of Carton]**

**Evergreen II Spot on for Dogs**

[Note to reviewer: The word "Dogs" in the product brand name will be at least 75% the height of the largest letter in the primary brand name]

[Note to reviewer: Alternate Brand Names are listed at the end of this document on page 10]

[Note to reviewer: A large clear picture of a dog in the weight range for the product as packaged will be included on the front panel]

**Monthly Topical Treatment of Fleas, Ticks, Mosquitoes, Biting Flies and Lice**

**For use only on dogs and puppies 7 weeks of age and older and [4-10 lbs] [11-20 lbs]  
[21-55 lbs] [over 55 lbs]**

**ACTIVE INGREDIENTS:**

Imidacloprid .....	7.12 %
Permethrin* .....	35.6 %
Pyriproxyfen .....	0.36 %
<b>OTHER INGREDIENTS .....</b>	<b>56.92 %</b>
<b>TOTAL .....</b>	<b>100.00 %</b>

\*cis/trans ratio: max 55% (±) cis and min 45% (±) trans

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

See First Aid and Directions for Use on back panel.

**NET CONTENTS:** [X fl oz (Y mL)]

[One] [Three] [Four] [Five] [Six] [Eight] [Ten] [Twelve] Tubes

[0.016 fl oz (0.48 mL)] [0.041 fl oz (1.2 mL)] [0.101 fl oz (3.0 mL)] [0.162 fl oz (4.8 mL)]

[1.5 cm x 1.5 cm cat prohibition icon]

**DO NOT USE ON CATS**

[Note to reviewer: A [1.5cm x 1.5 cm] cat prohibition icon in a box located at the lower right hand corner of the front panel in yellow with black images will be placed]

**ACCEPTED**

**02/02/2017**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended for the  
pesticide registered under

EPA Reg. No. **92334-1**

**[Front or Back Panel of the Carton]**

Evergreen Animal Health, LLC  
22655 Centennial Road  
Gretna, Nebraska 68028

EPA Reg. No. 92334-I  
EPA Est. No. XXXXX-XXX-XX

[Contains Imidacloprid, Permethrin, and Pyriproxyfen, the active ingredients found in K9Advantix II for Dogs\*]

\*This product is not manufactured or distributed by Bayer, the maker of K9Advantix<sup>®</sup> II for Dogs. K9Advantix<sup>®</sup> II for Dogs is a registered trademark of Bayer.]

[Note to reviewer: When the above optional claim is used, all three statements included in this optional claim will be on the same panel]

[Note to reviewer: Additional optional text/claims listed on pages 7 through 9]

**[Back Panel of the Carton]**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

**WARNING:** Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**HAZARDS TO DOMESTIC ANIMALS**

**For external use on dogs only. Do not use on animals other than dogs.** Do not use on dogs or puppies under seven weeks of age or weighing less than [4 lbs] [11 lbs] [21 lbs] [55 lbs]. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities may occur after using **ANY** pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

**ENVIRONMENTAL HAZARDS**

This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product packaging.



FIRST AID	
If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
If swallowed	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
If on skin or clothing	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-XXX-XXXX.	
NOTE TO PHYSICIAN OR VETERINARIAN	
Treat patient symptomatically	

**Side Effects:** Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Although uncommon, gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-xxx-xxxx.

[Note to reviewer: A box labeled "Side Effects" will be placed immediately above the cat warning text box on the back panel of the carton.]

[1.5 cm x 1.5 cm cat prohibition icon]  
**DO NOT USE ON CATS-MAY BE FATAL.**  
Keep cats away from treated dogs for 24 hours.  
If applied to a cat or ingested by a cat, contact your veterinarian immediately.

[Note to reviewer: A [1.5 cm x 1.5 cm] cat prohibition icon and warning text box will be located at the lower right hand corner of the back panel of the carton in yellow with black images and text.]

**[Back Panel of the Carton]**

**PRODUCT INFORMATION**

Evergreen II Spot On for Dogs rapidly kills fleas and may reduce the incidence of flea allergy dermatitis (FAD), a hypersensitivity skin disorder which may be induced by the feeding activity of fleas. Evergreen II Spot On for Dogs kills existing fleas on dogs within 12 hours. Any other fleas that jump on the dog are killed within 2 hours. Protection against further flea infestation lasts at least four (4) weeks.

Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climate. Flea larvae in the dog's surroundings are killed following contact with an Evergreen II Spot On for Dogs treated dog. Evergreen II Spot On for Dogs is waterproof and will remain effective even after a shampoo treatment, after swimming or after exposure to rain or sunlight. For best results, use monthly treatments for flea and tick control.

**Monthly Topical Treatment of Fleas, Ticks, Mosquitoes, Biting Flies and Lice**

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS.

**RESTRICTIONS**

Do not use on cats.

Do not allow your dog to ingest this product.

Do not get this product in your dog's eyes.

Do not use on dogs under seven weeks of age or weighing less than [4 lbs] [11 lbs] [21 lbs] [55 lbs].

Do not apply more than 1 tube per treatment per dog.

Do not apply more than 1 tube per treatment for dogs over 55 lbs. [This restriction will appear only on the package for dogs over 55 lbs.]

[Note to reviewer: either a plastic tube or aluminum tube will be chosen to use for the final product package]

**[How to apply directions for plastic tube container:]**

**How to Apply**

The dog should be standing for the application. Remove tube from the package. Hold tube in a vertical upright position. Cut off top of tube with scissors. Part the hair at each spot until the skin is visible. Invert tube and place the open end of the tube on the skin of the dog. Squeeze tube to expel the entire content of liquid and apply the product evenly along the dog's back in 3 to 4 spots from the base of the skull to the base of the tail. Take care that liquid does not run off the dog. Avoid contact with treated area until dry.

**[How to apply direction for aluminum/plastic tube container:]****How to Apply**

The dog should be standing for the application. Remove tube from the package. Hold tube in a vertical upright position. Screw [Pull] cap off of tube. While maintaining the tube in upright position, turn cap and puncture end of tube. Invert tube and apply the entire content of liquid to the skin of the dog evenly along the dog's back as a line from the base of the skull to the base of the tail. Take care that liquid does not run off the dog. Avoid contact with treated area until dry.

Discard empty tube as described in Storage and Disposal. In case of severe pest infestations, you are able to retreat your dog earlier than (4) four weeks. If infestation is severe at the initiation of treatment, once a week treatment is permitted not to exceed 4 weeks. After pest control has been successful, please return to a monthly retreatment schedule.

[Note to reviewer: A dog icon that shows the application may be added to this section "how to Apply"]

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**Storage:** Store in a cool, dry place inaccessible to children and pets. Protect from freezing.

**Pesticide Disposal and Container Handling:** Nonrefillable container.

**If empty:** Do not reuse this container.

Place in trash or offer for recycling, if available.

**If partly filled:** Call your local solid waste agency or 1-800-XXX-XXXX for disposal instructions.

**Never place unused product down any indoor or outdoor drain.**

**[LIMITED WARRANTY AND LIMITATION OF DAMAGES**

Evergreen Animal Health, LLC warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW EVERGREEN MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Evergreen is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law, any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.]

[For consumer questions call 1-800-XXX-XXXX]

[For medical emergencies call 1-800-XXX-XXXX]

**[Tube Label]**

**Evergreen II Spot On for Dogs**

[4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs] and 7 weeks & older

35.6% permethrin  
7.12% imidacloprid  
0.36% pyriproxyfen

[0.016 fl oz (0.48 mL)] [0.041 fl oz (1.2 mL)] [0.101 fl oz (3.0 mL)] [0.162 fl oz (4.8 mL)]

EPA Reg. No. 92334-1

Cat prohibition icon [Do not use on cats.]

Keep Out of Reach of Children

WARNING

Read Entire Label Before Use

Lot #

["For external use only"]

[Note to reviewer: If there is still room on the tube, the phrase "For external use only" will be added to the tube label.]

**[Optional/Alternate Claims, which may appear on carton]**

- 1) For the prevention and treatment of Ticks, Fleas, Mosquitoes, Biting Flies and Lice on Dogs
- 2) Topical prevention and treatment of ticks, fleas and mosquitoes for dogs and puppies 7 weeks of age and older weighing [4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs]
- 3) Preventative [treatment][control] of [ticks],[fleas], [mosquitoes][biting flies],and[lice] for monthly use on dogs and puppies 7 weeks of age and older weighing [4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs]
- 4) Repels and kills [Kills and repels] ticks including Deer ticks [vector of Lyme disease], Brown dog ticks [vector of Ehrlichiosis], American dog ticks [vector of Rocky Mountain spotted fever], and Lone Star ticks [vector of Ehrlichiosis] for up to four weeks [for up to one month]
- 5) Evergreen II Spot On for Dogs contains imidacloprid, permethrin, and [an/the] [insect growth regulator] [IGR] pyriproxyfen
- 6) Evergreen II Spot On for Dogs contains [an] [the] [insect growth regulator] [IGR] [pyriproxyfen]
- 7) [One] [A] [single] [topical] application remains effective [for] [a month][four {4} weeks]
- 8) [One] [A] [single] [topical] application is effective [for] [a month][four {4} weeks]
- 9) Convenient [and easy] to [use] [apply] [Spot on [solution]] [topical [solution]]
- 10) Easy to [use] [apply] [Spot on [solution]] [topical [solution]]
- 11) [One] [A] [single] [topical] [application] prevents fleas [and flea [re-]infestations] [for] [a month][four {4} weeks]
- 12) [One] [A] [single] [topical] [application] prevents [fleas and ] flea [re-]infestations [for] [a month][four {4} weeks]
- 13) [One] [A] [single] [topical] [application] prevents ticks [and tick [re-]infestations] [for] [a month][four {4} weeks]
- 14) [One] [A] [single] [topical] [application] prevents [ticks and] tick [re-]infestations [for] [a month][four {4} weeks]
- 15) Dead fleas don't bite
- 16) [Kills] [and] [repels] fleas before they lay eggs
- 17) Dead fleas don't lay eggs
- 18) Prevents flea egg hatching
- 19) [Flea adulticide] [Flea larvicide] [and] [Flea ovicide]
- 20) Flea adulticide, larvicide and ovicide
- 21) [Repels] [Inhibits] [annoying] [bothersome] nuisance biting flies [and] [fleas] [and] [ticks]
- 22) [Still] [Remains] effective after swimming [and] [shampooing]
- 23) [Kills] [and] [prevents] [biting] [chewing] lice
- 24) Prevents further infestations of [biting] [chewing] lice
- 25) Fragrance free
- 26) [Contains] no Fragrance
- 27) Monthly topical treatment kills and repels fleas, ticks and mosquitoes
- 28) Kills and repels all life stages of fleas
- 29) Repels and kills all stages of fleas
- 30) Kills and Repels Fleas, Ticks & Mosquitoes [for up to one month] [for up to [four] {4} weeks]

- 31) Repels and Kills Ticks, Fleas & Mosquitoes [for up to one month] [for up to [four] [4] weeks]
- 32) Prevents fleas on dogs from infesting your home
- 33) Kills fleas on dogs within 12 hours and continues to prevent infestations for a month [for [four] [4] weeks]
- 34) Controls flea infestation for up to one month [for up to [four] [4] weeks]
- 35) Prevents development of fleas, flea eggs, larvae and pupae for up to one month [for up to [four] [4] weeks]
- 36) Prevents development of fleas for up to one month [for up to [four] [4] weeks]
- 37) Breaks flea life cycle for up to one month [for up to [four] [4] weeks]
- 38) Repels and kills mosquitoes for up to four weeks
- 39) Repels biting flies and prevents blood-feeding by biting flies
- 40) Water-proof
- 41) 5-way protection: Fleas, Ticks, Mosquitoes, Biting flies and Lice [insect icons may be used]
- 42) Kills chewing lice
- 43) Kills chewing lice & repels biting flies
- 44) Breaks the flea life cycle [graphic icon]
- 45) Easy to use Applicator [Image]
- 46) For Dogs and Puppies 7 weeks of age and older weighing [4-10 lbs] [11-20 lbs] [21-55 lbs] [over 55 lbs]
- 47) Small Dog [4-10 lbs]
- 48) Medium Dog [11-20 lbs]
- 49) Large Dog [21-55 lbs]
- 50) Extra Large Dog [over 55 lbs]
- 51) [For up to 1 month][4 weeks]: [Kills & Repels] [Repels & Kills] Fleas, Flea Eggs, Ticks and Mosquitoes
- 52) [For up to 1 month][4 weeks]: [Prevents] [Repels] Biting Flies and [prevents] [and] [&] [kills] Lice

[Optional graphic images or icons:]



Fleas [Flea]	 FLEAS	
Flea eggs	 FLEA EGGS	
Ticks [Tick]	 TICKS	
Lice [Louse]	 LICE	
Repels Biting Flies [Biting Fly]	 REPELS BITING FLIES	
Mosquitoes [Mosquito]	 MOSQUITOES	

Image of flea life cycle  
 Do Not Use on Cat prohibition icon  
 Tube, Tubes  
 Application procedures

**[Alternate Brand Names:]**

Evergreen II Small Dog  
Evergreen II Medium Dog  
Evergreen II Large Dog  
Evergreen II Extra Large Dog  
Evergreen III Spot on for Dogs  
Activate II for Dogs  
Advance II For Dogs  
Activate III for Dogs  
Truveta III for Dogs  
Activetix II for Dogs  
Truветix III for Dogs  
ActiGuard III for Dogs  
Vetix III for Dogs  
AvanTect II for Dogs  
VanTect II for Dogs  
Vantect II for Dogs  
K9 Evergreen II Spot on for Dogs  
K9 Evergreen III Spot on for Dogs  
K9 Activate II for Dogs  
K9 Advance II For Dogs  
K9 Activate III for Dogs  
K9 Truveta III for Dogs  
K9 Activetix II for Dogs  
K9 Truветix III for Dogs  
K9 ActiGuard III for Dogs  
K9 Vetix III for Dogs  
K9 AvanTect II for Dogs  
K9 VanTect II for Dogs  
K9 Vantect II for Dogs





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

30-January-2017

Robert Scharf, Managing Director  
Evergreen Animal Health, LLC  
22655 Centennial Road  
Gretna, NE 68028

Product Name: Evergreen II Spot On for Dogs  
EPA Reg. No.: 92334-R  
Application Date: 20-April-2016  
Decision Number: 516525

Dear Mr. Scharf:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application cannot be approved unless revisions are made to the label. The necessary label changes are specified on the attached label.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

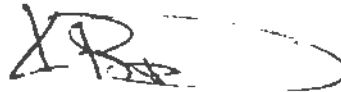
- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at [Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', with a large, sweeping flourish extending to the right.

Kable Bo Davis, Product Manager 3  
Invertebrate and Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs

attachments

## Breeden-Alemi, Julie

---

**From:** Jones, Ricardo  
**Sent:** Wednesday, February 01, 2017 2:59 PM  
**To:** Breeden-Alemi, Julie  
**Subject:** RE: DCIs/EDSPs Imidacloprid

Sure thing, here's the list of the rest of the DCIs that are still showing as open in PRISM. I didn't enter these and haven't updated them since taking over this a.i. a few months ago, so I can't say for certain that they are definitely active. EDSP is weird in that I don't really know much about what is going on for my chemicals.

### EDSP

129099-1220 (Willowood)  
129099-177 (Ensysnex III)  
129099-179 (Albaugh)  
129099-181 (Amtide)  
129099-182 (ADAMA Celcius)  
129099-184 (Bayer Cropscience)  
129099-436 (Nufarm)  
129099-437 (Nufarm Limited)  
129099-439 (UPI)  
129099-440 (Rotam)  
129099-441 (Sharda Cropchem)

*Re Carolyn Dutta, July 16  
just need to list the one  
in Registration Notice  
2/1/17*

### Reg Review

129099-951 (all)  
129099-1516 (Duplicate DCI issued to Willowood)

**From:** Breeden-Alemi, Julie  
**Sent:** Tuesday, January 31, 2017 11:11 AM  
**To:** Jones, Ricardo <Jones.Ricardo@epa.gov>  
**Subject:** RE: DCIs/EDSPs Imidacloprid

Thank you Ricardo! Indeed we do list the EDSPs in the registration notice. Can you please provide?

**From:** Jones, Ricardo  
**Sent:** Tuesday, January 31, 2017 10:38 AM  
**To:** Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>  
**Subject:** RE: DCIs/EDSPs Imidacloprid

Julie,

The registration review DCI (ongoing) is GDCI# 129099-951.

There are also EDSP DCIs out there. These are issued a little differently (different number per registrant), and there are a bunch. However, I don't think RD normally cites these DCIs (I could be wrong), but let me know if you need any more info about these.

Ricardo

**From:** Breeden-Alemi, Julie  
**Sent:** Tuesday, January 31, 2017 7:08 AM  
**To:** Jones, Ricardo <[Jones.Ricardo@epa.gov](mailto:Jones.Ricardo@epa.gov)>  
**Subject:** DCIs/EDSPs Imidacloprid

Good morning Ricardo!

I hope you are having a great week thus far.

It looks like you are the CRM for imidacloprid. I have a PRIA action to register a new product containing imidacloprid. Could you please tell me the current GDCIs and EDSPs that are unfulfilled? I must list them on the registration notice. I need only the number designations such as: GDCI-129099-1516

Thank you for your efforts,  
Julie

---

**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511  
Office: S-7216, Mail Code: 7505P

## Breeden-Alemi, Julie

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**From:** Olaf Hansen <olaf.hansen@convet.de>  
**Sent:** Tuesday, January 31, 2017 9:12 AM  
**To:** Breeden-Alemi, Julie  
**Cc:** Davis, Kable; IVB1; 'Bob Scharf'; 'F. Terry McNamara'  
**Subject:** AW: 92334-R Final Label proposal  
**Attachments:** Final\_Label\_92334-R\_Evergreen Spot on\_Jan 31-2017.pdf

Dear Julie,

thanks for your support over the last days.

We accept all label changes. Please find enclosed an updated label ready to be stamped.

Best regards,  
Olaf

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Evergreen Animal Health, LLC  
Dr. med. vet. Olaf Hansen, MBA  
22655 Centennial Road  
Gretna, Nebraska 68028

Tel. +49 2173 20 40 990  
Fax: +49 2173 20 40 997  
E-Mail: [Olaf.Hansen@ConVet.de](mailto:Olaf.Hansen@ConVet.de)

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**Von:** Breeden-Alemi, Julie [mailto:[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)]  
**Gesendet:** Montag, 30. Januar 2017 22:37  
**An:** Olaf Hansen <olaf.hansen@convet.de>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>  
**Betreff:** RE: 92334-R Final Label proposal

Hi Olaf,

Thank you for your attention to this label and process today. Please find attached the label comments as we discussed on the phone as well as the Pre-Decisional letter. We have made wonderful progress today. Tomorrow I will be able to continue with the action once I receive the revised label.

Have a nice evening,

## Breeden-Alemi, Julie

---

**From:** Olaf Hansen <olaf.hansen@convet.de>  
**Sent:** Monday, January 30, 2017 4:21 PM  
**To:** Breeden-Alemi, Julie  
**Subject:** Claims 51 and 52

- 1) [For up to 1 month][4 weeks]: [Kills & Repels] [Repels & Kills] Fleas, Flea Eggs, Ticks and Mosquitoes
- 2) [For up to 1 month][4 weeks]: [Prevents] [Repels] Biting Flies and [prevents] [and] [&] [kills] Lice



## Breeden-Alemi, Julie

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**From:** Jones, Ricardo  
**Sent:** Monday, January 09, 2017 2:53 PM  
**To:** Breeden-Alemi, Julie  
**Subject:** RE: Pyriproxyfen EDSP and GDCI

That's correct. The info below is for GDCI 129032-1299. There is also an EDSP DCI. It is #129032-187 (it is a List 1 EDSP chemical). All of the data has been received for that DCI, and both an EDSP WOE document and DER were posted to the docket in 2015. Here's a link to the docket: <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2011-0677>

**From:** Breeden-Alemi, Julie  
**Sent:** Monday, January 09, 2017 1:00 PM  
**To:** Jones, Ricardo <Jones.Ricardo@epa.gov>  
**Subject:** RE: Pyriproxyfen EDSP and GDCI

Thank you Ricardo! Do these studies apply to DCI 129032-1299? Are there any active EDSPs?  
Enjoy your day,  
Julie

**From:** Jones, Ricardo  
**Sent:** Friday, January 06, 2017 4:47 PM  
**To:** Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>  
**Subject:** RE: Pyriproxyfen EDSP and GDCI

Julie,

I am the correct contact. Below is my DCI tracking table. Hopefully it can give you some useful info. It hasn't been updated in a couple of months, so if you have any specific questions, feel free to ask.

DCI mailed (PRISM): 2/21/13 - to OMB  
90 Day GDCI response: complete  
Technical Data Doer: Valent USA

Method	Study Description	Due Date	Notes
SS850.1000	Chronic freshwater sediment testing	9/30/2016	Extension requested to Sep 2016. Extension requestd to Dec 28, 2016. Leptocheirus report received 5/13/16 (DP436773), awaiting Chironomus spec.
SS-1154	Acute honey bee larvae feeding study	1/31/2016	Waiver requested (DP413410) - denied  Submitted January 2016, MRID 49808101 (DP432598)
850.1710	Oyster BCF	1/31/2016	Under Review - DP432597 (3/30/16)

850.4225	Seedling emergence, Tier II	2/21/2014	Under review - DP 419037 (4/1/14)
850.4250	Vegetative vigor, Tier II	2/21/2014	Under review - DP 419039 (4/1/14)
870.6200	Neurotoxicity screening battery	2/21/2014	8/8/13, <b>Satisfied</b> by earlier studies (D3988085 and D413818)
870.7800	Immunotoxicity	2/21/2014	8/8/13, Satisfied by earlier studies (D3988085 and D413819)

Voluntary submissions (pending) Bumble bee acute oral & contact, chronic honey bee test, pollinator residue tests for: Cotton, Citrus, and Apple

**From:** Breeden-Alemi, Julie  
**Sent:** Friday, January 06, 2017 4:25 PM  
**To:** Jones, Ricardo <[Jones.Ricardo@epa.gov](mailto:Jones.Ricardo@epa.gov)>  
**Subject:** FW: Pyriproxyfen EDSP and GDCI

Hi!

Could you please tell me if you are the correct person to contact to determine the current active GDCIs/EDSPs for Pyriproxyfen? We have several actions that require this information in a fairly timely manner. Can you provide guidance?

Many thanks!  
Julie

---

Julie A. Breeden-Alemi, DVM  
U.S. Environmental Protection Agency  
OCSP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511  
Office: S-7216, Mail Code: 7505P

**From:** Aubuchon, Matthew  
**Sent:** Wednesday, December 21, 2016 11:14 AM  
**To:** Jones, RDavid <[Jones.Rdavid@epa.gov](mailto:Jones.Rdavid@epa.gov)>  
**Cc:** Ciarlo, Timothy <[Ciarlo.Timothy@epa.gov](mailto:Ciarlo.Timothy@epa.gov)>; Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>; Fertich, Elizabeth



## Breeden-Alemi, Julie

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**From:** Gaines, Jennifer  
**Sent:** Wednesday, January 25, 2017 4:10 PM  
**To:** Breeden-Alemi, Julie  
**Subject:** FW: Permethrin EDSP and GDCI

Jennifer Gaines  
Wildlife Biologist  
Registration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
(703) 305-5967

**From:** Pruitt, Brittany  
**Sent:** Tuesday, January 24, 2017 5:34 PM  
**To:** Gaines, Jennifer <[gaines.jennifer@epa.gov](mailto:gaines.jennifer@epa.gov)>  
**Subject:** RE: Permethrin EDSP and GDCI

Hi Jen,

For Permethrin, the POTW special study from GDCI-109701-1252 is the only study that is out right now for those listed DCIs. I am going to reach out to the task force for an update. I don't have PBO anymore. Maria Piansay does. The POTW was a joint with PBO, but I'm not sure if there are other outstanding data requirements for PBO.

Brittany

**From:** Gaines, Jennifer  
**Sent:** Tuesday, January 24, 2017 6:48 AM  
**To:** Pruitt, Brittany <[Pruitt.Brittany@epa.gov](mailto:Pruitt.Brittany@epa.gov)>  
**Subject:** FW: Permethrin EDSP and GDCI

Hi Brittany,

I have a PRIA coming up very soon for a new product and am trying to determine whether the DCIs and EDSPs listed below are still outstanding (have all the data been submitted)?

Thanks!  
Jen

Jennifer Gaines  
Wildlife Biologist  
Registration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
(703) 305-5967

**From:** Breeden-Alemi, Julie  
**Sent:** Tuesday, January 24, 2017 6:42 AM  
**To:** Gaines, Jennifer <[gaines.jennifer@epa.gov](mailto:gaines.jennifer@epa.gov)>  
**Subject:** FW: Permethrin EDSP and GDCI

**From:** Pruitt, Brittany  
**Sent:** Thursday, December 22, 2016 10:52 AM  
**To:** Aubuchon, Matthew <[Aubuchon.Matthew@epa.gov](mailto:Aubuchon.Matthew@epa.gov)>  
**Cc:** Fertich, Elizabeth <[fertich.elizabeth@epa.gov](mailto:fertich.elizabeth@epa.gov)>; Ciarlo, Timothy <[Ciarlo.Timothy@epa.gov](mailto:Ciarlo.Timothy@epa.gov)>; Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>  
**Subject:** RE: Permethrin EDSP and GDCI

Hi all,

These are the DCIs for permethrin by action. Let me know if you have any more questions.

**DCI for Residential Exposure Joint Venture (REJV)**

**DCI for Registration Review**

**DCI for EDSP Test Orders**

- a. Permethrin GDCI-109701-1113
- b. Permethrin GDCI-109701-1252
- c. Permethrin GDCI-109701-1281
- d. Permethrin EDSP-109701-83
- e. Permethrin EDSP-109701-84
- f. Permethrin EDSP-109701-85
- g. Permethrin EDSP-109701-86
- h. Permethrin EDSP-109701-87
- i. Permethrin EDSP-109701-88
- j. Permethrin EDSP-109701-89
- k. Permethrin EDSP-109701-90
- l. Permethrin EDSP-109701-91
- m. Permethrin EDSP-109701-92

Best,

Brittany Pruitt  
Chemical Review Manager  
Pesticide Re-evaluation Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
(703) 347-0289  
[pruitt.brittany@epa.gov](mailto:pruitt.brittany@epa.gov)

**From:** Aubuchon, Matthew  
**Sent:** Wednesday, December 21, 2016 11:20 AM  
**To:** Pruitt, Brittany <[Pruitt.Brittany@epa.gov](mailto:Pruitt.Brittany@epa.gov)>

## Breeden-Alemi, Julie

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**From:** Terry McNamara <tmcnamara@exponent.com>  
**Sent:** Thursday, January 26, 2017 1:10 PM  
**To:** Breeden-Alemi, Julie  
**Cc:** Olaf Hansen (olaf.hansen@convet.de) (olaf.hansen@convet.de)  
**Subject:** RE: EPA File Symbol No. 92334-R  
**Attachments:** Evergreen data matrix 8570-35 Data Matrix EPA Version\_signed.pdf; Pages from Releasable 11556-141 vol 3.pdf

Hi Julie,

Olaf asked me to respond to your question below.

The companion animal safety studies supporting the weekly treatment interval are MRID 450097101 and 45563003. These studies are highlighted on page 2 of the attached data matrix submitted with the application for registration.

Also for your ease of reference, attached is an Agency review citing these two studies and summarizing that in these two studies the animals were treated 4 times at weekly intervals.

If I can provide anything else, please don't hesitate to contact me.

*Thanks,  
Terry Mc*

**From:** Olaf Hansen [mailto:olaf.hansen@convet.de]  
**Sent:** Thursday, January 26, 2017 12:06 PM  
**To:** Terry McNamara  
**Subject:** WG: EPA File Symbol No. 92334-R

Have we?

---

**Von:** Breeden-Alemi, Julie  
**Gesendet:** 26.01.2017 17:43  
**An:** [Olaf Hansen](mailto:olaf.hansen@convet.de)  
**Cc:** [Davis, Kable](#)  
**Betreff:** RE: EPA File Symbol No. 92334-R

Good morning Olaf,

On 10 January 2017 we received a document with several responses to some of our previous label comments. In response #8 you reference a study that speaks to the weekly treatment interval for the product. Is that study cited on your current data matrix? If it is, please provide the MRID #.

Many thanks,  
Julie

---

Julie A. Breeden-Alemi, DVM

U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

---

**From:** Olaf Hansen [<mailto:olaf.hansen@convet.de>]  
**Sent:** Friday, January 20, 2017 4:17 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>; 'Terry McNamara' <[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)>  
**Cc:** 'Mary Hunt' <[mhunt@exponent.com](mailto:mhunt@exponent.com)>  
**Subject:** AW: EPA File Symbol No. 92334-R

Hello Julie,

I hope everything is fine and you are satisfied with our answers.

Please let me know if you need any further information or if you want to discuss some points on the phone.

Enjoy your weekend!

Best regards,  
Olaf

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Evergreen Animal Health, LLC  
Dr. med. vet. Olaf Hansen, MBA  
22655 Centennial Road  
Gretna, Nebraska 68028

Tel: +49 2173 20 40 990  
Fax: +49 2173 20 40 997  
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**Von:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Gesendet:** Donnerstag, 12. Januar 2017 14:11  
**An:** Terry McNamara <[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)>  
**Cc:** Olaf Hansen ([olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)) ([olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)) <[olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)>; Mary Hunt <[mhunt@exponent.com](mailto:mhunt@exponent.com)>  
**Betreff:** RE: EPA File Symbol No. 92334-R

Thank you very much, documents received! I am working on this today and into next week. I'll be in touch ASAP to continue this momentum!

Enjoy your day,  
Julie

---

Julie A. Breeden-Alemi, DVM  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

---

**From:** Terry McNamara [<mailto:tmcnamara@exponent.com>]  
**Sent:** Tuesday, January 10, 2017 5:55 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)> *1 - 10*  
**Cc:** Olaf Hansen ([olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)) ([olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)) <[olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)>; Mary Hunt <[mhunt@exponent.com](mailto:mhunt@exponent.com)>  
**Subject:** RE: EPA File Symbol No. 92334-R

Julie,

Attached is a clean version of the revised label.

Attached is a marked up version showing the changes in track change mode (all the German (Olaf) terms pertain to formatting).

There are still 9 areas of question or discussion, and we thought the best way to discuss these items is simply to lay them out in a document. Accordingly, this discussion is attached.

If we can provide any clarification, information, etc., please don't hesitate to contact us. We really appreciate how you have been so responsive.

Thanks  
Terry Mc

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**From:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Sent:** Tuesday, January 10, 2017 12:37 PM  
**To:** Terry McNamara  
**Subject:** RE: EPA File Symbol No. 92334-R

Thank you for the update Terry!  
Julie

---

**From:** Terry McNamara [<mailto:tmcnamara@exponent.com>]  
**Sent:** Tuesday, January 10, 2017 12:34 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Julie,

Thank you for the note; it is very helpful. We were aware of the Monday holiday but did not think about the inauguration (being outside of DC, we usually don't think about such things, but I have now seen notices that our Exponent DC office is closed because of the parade and all the other events that will be taking place Friday).

We have been working on the label, and have completed a rough draft version. Almost all of the changes you recommended have been made, but there are still a few issues, and we also want to address your questions. We are hopeful of finalizing the revised labeling and providing an explanation to send to you today. I am still waiting on some items from Olaf (he is in Germany), and consequently I think getting the response to you today may be too optimistic. Nonetheless, I do think we should have a revised label and to address all the comments tomorrow via email to you tomorrow.

This is Evergreen's only product, and they are very eager for registration and want to provide anything we can to help the process.

Thanks  
Terry Mc

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**From:** Breeden-Alemi, Julie [mailto:[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)]  
**Sent:** Tuesday, January 10, 2017 6:55 AM  
**To:** Terry McNamara  
**Subject:** FW: EPA File Symbol No. 92334-R

Good morning Terry,

I'm just following up to the email and label comments and questions sent 1/4/17. As a courtesy I want to let you know that the Pre-Decisional date for this action is 1/30/17. Next week is an interesting week as we have two holidays plus inauguration events happening. If you have the time, and we are able to make a bit of headway this week it would serve us well.

Thanks so much and have a nice day,  
Julie

---

Julie A. Breeden-Alemi, DVM  
U.S. Environmental Protection Agency  
OCSP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

---

**From:** Breeden-Alemi, Julie  
**Sent:** Wednesday, January 04, 2017 4:32 PM  
**To:** 'Terry McNamara' <[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Terry,

Please find attached initial label comments regarding EPA File Symbol No. 92334-R. Please send both clean and highlighted revised readable electronic pdf labels. Let me know if you have any questions.

Please include comments regarding these questions **when you send the revised label**:

1. Please describe the packaging for the product.
  - a. "Front Panel" and "Back Panel" ... do these refer to a box=carton?
  - b. When is the insert used and when is it not used
    - i. What information is included in the insert when it is used?
  - c. Are the tubes all free from one another or are there strips of 3 for example?
  - d. Is the single applicator option packaged the same way as the packages of multiples or differently?
  - e. Is there any difference in the plastic tube vs. aluminum tube with degree of CRP?
2. Several of the Alternate Brand Names are listed as a II or III, but I am unable to find a I in existence. For example, Activate II for Dogs and Activate III for Dogs are both listed as ABNs for this product. Why is there a II and III for the same product? Why is there no Activate I? Can you please comment?

Many thanks,  
Julie

---

Julie A. Breeden-Alemi, DVM  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

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**From:** Terry McNamara [<mailto:tnmcnamara@exponent.com>]  
**Sent:** Thursday, December 29, 2016 12:56 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Julie,

Thanks for your follow up and email.

As we stated in the pre registration meeting for this product, no new claims were going to be made; the same claims based on the same already reviewed and accepted data was the mantra.

I look forward to getting your comments, and I hope we can turn them around quickly.

Thanks again,  
Terry Mc

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**From:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Sent:** Thursday, December 29, 2016 11:58 AM  
**To:** Terry McNamara  
**Cc:** Davis, Kable; IVB1  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Terry,

Last week in your voicemail you asked about an efficacy review.

There is no efficacy review for this action. The submitted data matrix matches that of the cited label, and the submission for this action stated that only claims present on the cited label would be included on the submitted label (no new claims, no new data).

I have label comments ready for you, but I have to check on one thing with Bo Davis before I send them. I plan on sending them early next week!

Many thanks,  
Julie

---

**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

---

**From:** Breeden-Alemi, Julie  
**Sent:** Thursday, December 22, 2016 4:22 PM  
**To:** 'Terry McNamara' <[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)>  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Terry,

I received your voicemail this morning. I will look into your question about efficacy and touch base with you next week. I am hoping to be able to start working on the label next week as well!

Happy holidays,  
Julie

---

**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

---

**From:** Olaf Hansen [<mailto:olaf.hansen@convet.de>]  
**Sent:** Wednesday, December 21, 2016 1:20 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>; 'Bob Scharf' <[bob@scharf1.com](mailto:bob@scharf1.com)>; 'F. Terry McNamara' <[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)>  
**Subject:** AW: EPA File Symbol No. 92334-R

Dear Julie,

everything worked well, Thank you very much!

Terry will get in contact with you concerning the label.

Happy Holidays  
Olaf

---

**Von:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Gesendet:** Dienstag, 20. Dezember 2016 20:28



**An:** Olaf Hansen <olaf.hansen@convet.de>  
**Cc:** Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; 'Bob Scharf' <bob@scharf1.com>  
**Betreff:** RE: EPA File Symbol No. 92334-R

Here are the requested documents! Passwords to follow in a separate email.

Enjoy the afternoon,  
Julie

---

**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

---

**From:** Olaf Hansen [<mailto:olaf.hansen@convet.de>]  
**Sent:** Tuesday, December 20, 2016 1:37 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>; 'Bob Scharf' <[bob@scharf1.com](mailto:bob@scharf1.com)>  
**Subject:** AW: EPA File Symbol No. 92334-R

Yes ☺

Thank you  
Olaf

---

**Von:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Gesendet:** Dienstag, 20. Dezember 2016 19:08  
**An:** Olaf Hansen <olaf.hansen@convet.de>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>; 'Bob Scharf' <[bob@scharf1.com](mailto:bob@scharf1.com)>  
**Betreff:** RE: EPA File Symbol No. 92334-R

Oh, sorry, Olaf, I misunderstood! If you are saying it is ok to send by email, I will have to send it password protected, no choice. Is that what you want?  
Julie

---

**From:** Olaf Hansen [<mailto:olaf.hansen@convet.de>]  
**Sent:** Tuesday, December 20, 2016 1:03 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>; 'Bob Scharf' <[bob@scharf1.com](mailto:bob@scharf1.com)>  
**Subject:** AW: EPA File Symbol No. 92334-R

Hi Julie,

yes, but you can send them also via pdf.

Thanks  
Olaf

---

**Von:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Gesendet:** Dienstag, 20. Dezember 2016 18:52  
**An:** Olaf Hansen <[olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>  
**Betreff:** RE: EPA File Symbol No. 92334-R

Hi Olaf,  
The address to use would be the one in your signature, correct?  
Thanks!  
Julie

---

**From:** Olaf Hansen [<mailto:olaf.hansen@convet.de>]  
**Sent:** Tuesday, December 20, 2016 12:49 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>; 'Terry McNamara' <[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)>; 'Bob Scharf' <[bscharf@tevrabrands.com](mailto:bscharf@tevrabrands.com)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>  
**Subject:** AW: EPA File Symbol No. 92334-R

Hello Julie,

thanks for doing it so quickly. Please send the reviews to my hands. No need for password protected pdfs.

Thanks  
Olaf

Best regards,  
Olaf

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Evergreen Animal Health, LLC  
Dr. med. vet. Olaf Hansen, MBA  
22655 Centennial Road  
Gretna, Nebraska 68028

Tel: +49 2173 20 40 990  
Fax: +49 2173 20 40 997  
E-Mail: [Olaf.Hansen@ConVet.de](mailto:Olaf.Hansen@ConVet.de)

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The preceding e-mail message (including any attachments) contains information that may be confidential, or constitute non-public information. It is intended to be conveyed only to the designated recipient(s). If you are not an intended recipient of this message, please notify the sender by replying to this message and then delete it from your system. Use, dissemination, distribution, or reproduction of this message by unintended recipients is not authorized and may be unlawful.

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**Von:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Gesendet:** Dienstag, 20. Dezember 2016 17:12  
**An:** Terry McNamara <[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)>; Bob Scharf (<[bscharf@tevrabrands.com](mailto:bscharf@tevrabrands.com)>); Olaf Hansen <[olaf.hansen@convet.de](mailto:olaf.hansen@convet.de)>

**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>

**Betreff:** EPA File Symbol No. 92334-R

Hello,

I am writing in response to a request for copies of the reviews associated with File Symbol No. 92334-R. Please address the following questions, and I will send the reviews to you ASAP.

1. The reviews you request do contain Confidential Business Information, and a specific request stating an acceptable mode of transmission for these documents is necessary. If you prefer password protected pdfs, you will have to state your preference in an email.
2. Could you please clarify for me to whom I should be primarily corresponding with when it comes to future emails?

Many thanks,  
Julie

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**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

## Breeden-Alemi, Julie

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**From:** Terry McNamara <tmcnamara@exponent.com>  
**Sent:** Wednesday, January 11, 2017 9:17 AM  
**To:** Breeden-Alemi, Julie  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Julie,

After I sent the revised label and discussion document late yesterday, I noted that there were a couple of questions in your email (below) that had not been addressed.

With regard to those questions not addressed,

- At this time an insert is not planned; all information will be on the box and tubes.
- In some instances the tubes may be connected in strips, like strips of 3 for example, and placed in the boxes, but in other instances the tubes may be "free" or placed in the boxes as single tubes. It is anticipated that multiple manufacturers/supplemental distributors may involved with the product and have different preferences. As CRP is not required for the packaging, the tubes may or may not be attached in strips.
- The current imidacloprid + permethrin + pyriproxyfen product on the market is branded as K9Advantix II (an improved version of K9Advantix – improved because it now contains pyriproxyfen), so we want to mirror the II. Additionally the product contains three actives – permethrin, imidacloprid and pyriproxyfen – and therefore we also considered to brand the product as III.

With these last responses, we believe we have addressed all your questions, but again, if there are any additional questions or information you would like, please don't hesitate to contact us. And, again, we really appreciate your efforts on this action.

*Thanks  
Terry Mc*

**From:** Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]  
**Sent:** Wednesday, January 04, 2017 4:32 PM  
**To:** Terry McNamara  
**Cc:** Davis, Kable; IVB1  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Terry,

Please find attached initial label comments regarding EPA File Symbol No. 92334-R. Please send both clean and highlighted revised readable electronic pdf labels. Let me know if you have any questions.

Please include comments regarding these questions **when you send the revised label:**

1. Please describe the packaging for the product.
  - a. "Front Panel" and "Back Panel" ... do these refer to a box=carton?
  - b. When is the insert used and when is it not used
    - i. What information is included in the insert when it is used?
  - c. Are the tubes all free from one another or are there strips of 3 for example?

- d. Is the single applicator option packaged the same way as the packages of multiples or differently?
  - e. Is there any difference in the plastic tube vs. aluminum tube with degree of CRP?
2. Several of the Alternate Brand Names are listed as a II or III, but I am unable to find a I in existence. For example, Activate II for Dogs and Activate III for Dogs are both listed as ABNs for this product. Why is there a II and III for the same product? Why is there no Activate I? Can you please comment?

Many thanks,  
Julie

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**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511

**From:** Terry McNamara [<mailto:tmcnamara@exponent.com>]  
**Sent:** Thursday, December 29, 2016 12:56 PM  
**To:** Breeden-Alemi, Julie <[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Julie,

Thanks for your follow up and email.

As we stated in the pre registration meeting for this product, no new claims were going to be made; the same claims based on the same already reviewed and accepted data was the mantra.

I look forward to getting your comments, and I hope we can turn them around quickly.

Thanks again,  
Terry Mc

**From:** Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]  
**Sent:** Thursday, December 29, 2016 11:58 AM  
**To:** Terry McNamara  
**Cc:** Davis, Kable; IVB1  
**Subject:** RE: EPA File Symbol No. 92334-R

Hi Terry,

Last week in your voicemail you asked about an efficacy review.

There is no efficacy review for this action. The submitted data matrix matches that of the cited label, and the submission for this action stated that only claims present on the cited label would be included on the submitted label (no new claims, no new data).

I have label comments ready for you, but I have to check on one thing with Bo Davis before I send them. I plan on sending them early next week!

Many thanks,  
Julie

## Breeden-Alemi, Julie

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**From:** Terry McNamara <tmcnamara@exponent.com>  
**Sent:** Friday, September 30, 2016 10:42 AM  
**To:** Breeden-Alemi, Julie  
**Cc:** Bacon, Laura; Olaf Hansen (olaf.hansen@convet.de) (olaf.hansen@convet.de); Bob Scharf (bscharf@tevrabrands.com); James Messina  
**Subject:** RE: File Symbol: 92334-R  
**Attachments:** Evergreen 8570-35 Data Matrix EPA Version\_signed.pdf; Evergreen Submission Cover Letter\_signed.pdf; Evergreen Confidential Attachment to Cover.pdf

Hello Julie,

I am a regulatory consultant (we have been in a few meetings together) working for Exponent who helped prepare the Evergreen submission.

Bob Scharf and Olaf Hansen asked me to call Laura in response to your email question below. Laura and I spoke this morning, and she recommended that I send the email response to you and copy in all parties.

The short answer is that certification that the packaging for 92334-R meets the child-resistant packaging standards in 40 CFR 157.32 is not necessary because 92334-R does not meet any of the toxicity criterion listed in 40 CFR 157.22 (a) for products requiring child-resistant packaging.

In explanation, the registration of this product is being based upon the acute toxicity data (cited in the data matrix; copy enclosed) of the Bayer 11556 – 141 formulation containing imidacloprid + permethrin + pyriproxyfen, and the acute toxicity of the Bayer 11556 – 116 formulation containing imidacloprid. This is detailed in the confidential attachment to the cover letter for the application (the cover letter and the confidential attachment are attached for your ready reference; please note the highlighted discussion in the confidential attachment). The acute toxicity data cited for these two Bayer formulations do not meet the toxicity criterion listed in 40 CFR 157.22(a).

In summary, the acute toxicity data to support the registration of EPA File Symbol 92334-R do not meet any of the toxicity criterion listed in 40 CFR 157.22 (a) for products requiring child-resistant packaging, and consequently CRP was not discussed in the application.

If I can provide any additional information on behalf of Evergreen, please don't hesitate to contact me, Bob or Olaf.

*Thanks*  
Terry McNamara  
Exponent, Inc  
Managing Regulatory Consultant  
Center for Chemical Regulation and Food Safety  
1150 Connecticut Avenue NW, Suite 1100  
Washington, DC 20036  
(913) 428 – 6229  
[tmcnamara@exponent.com](mailto:tmcnamara@exponent.com)

**From:** Bob Scharf [mailto:bob@scharf1.com]  
**Sent:** Thursday, September 29, 2016 10:12 AM  
**To:** 'Olaf Hansen'

**Cc:** Terry McNamara; James Messina  
**Subject:** FW: File Symbol: 92334-R

FYI

**From:** Bob Scharf (<mailto:bob@scharf1.com>)  
**Sent:** Thursday, September 29, 2016 9:02 AM  
**To:** 'Breedon-Alemi, Julie' <[Breedon-Alemi.Julie@epa.gov](mailto:Breedon-Alemi.Julie@epa.gov)>  
**Cc:** 'Bacon, Laura' <[Bacon.Laura@epa.gov](mailto:Bacon.Laura@epa.gov)>  
**Subject:** RE: File Symbol: 92334-R

Good morning Julie,

I apologize for having the email listed incorrectly. I'm sorry you had to call to get it straight but I appreciate you doing it as this registration is really important to our company.

My regulatory person is actually in transit to Germany right now so I can't reach him but I will track down our consultant and get back with you as soon as possible. I'm sorry it was not done properly. It does not seem that complicated and between our people and the consultant we sure should have been able to get it correct. I will get with the consultant and get the letter done right away.

Best regards,  
Bob  
402 215 5502

**From:** Breedon-Alemi, Julie (<mailto:Breedon-Alemi.Julie@epa.gov>)  
**Sent:** Thursday, September 29, 2016 8:12 AM  
**To:** [bob@scharf1.com](mailto:bob@scharf1.com)  
**Cc:** Bacon, Laura <[Bacon.Laura@epa.gov](mailto:Bacon.Laura@epa.gov)>  
**Subject:** File Symbol: 92334-R

Good morning, Bob,

Thank you for confirming your email address for me this morning.

Can you please tell me how you are addressing CRP for the new product: File Symbol 92334-R? I can't find a CRP Certification letter included in the package or anything on the Data Matrix. Please let me know if I'm missing something.

The following information should be included in a letter of Certification:

The actual CRP studies do not need to be submitted, but for each package configuration tested, the certification letter needs to include:

- The product name and EPA registration number
- Whether CRP is voluntary or required for the product
- Which package is associated with the CRP test data;
  - o A description of the package tested including a photograph of the package (including closure model and size, material specification, package color, Manufacturer, ASTM classification, size package tested with, and fill volumes);
- If you are employing any bridging rationales to cover certain packaging configurations, please explain.
- For the SAUE Testing,

- The directions on the package used for Senior Adult Use Effectiveness (SAUE) Testing along with any additional directions provided to the Seniors during SAUE Testing
- Number of seniors tested
- Percent able to open the package after the initial 5 minutes
- Percent able to open the package in the next one-minute trial
- For the CRE Test,
  - The number of children tested
  - Define the number of units that represent a child failure
  - The number of units a child receives at the beginning of the test
  - The number of failures
- The CRP certification statement: I certify that the packaging used for this product meets the standards of 40 CFR 157.32 including the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20 as published in 60 FR 37710 (July 21, 1995).
- Sign and date this certification on company letterhead

Thank you!  
Julie

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**Julie A. Breeden-Alemi, DVM**  
U.S. Environmental Protection Agency  
OCSPP / OPP / RD / IVB1  
[Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov)  
Phone: 703.347.0511



**Breeden-Alemi, Julie**

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**From:** Backus, Byron  
**Sent:** Wednesday, October 12, 2016 2:40 PM  
**To:** Breeden-Alemi, Julie; Fry, Meredith  
**Subject:** 92334-R

I missed the obvious. On page 4 of the data matrix dated 04/20/2016 the registrant cited the study in MRID 42178309. All the companion animal safety study data requirements have been satisfied.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

February 27, 2013

**MEMORANDUM:**

Subject: Name of Pesticide Product: K9 ADVANTIX PLUS 10  
EPA Reg. No. /File Symbol: 11556-141  
DP Barcode: DP 407747  
Decision No.: 473235  
Action Code: 360  
PC Codes: 129099 (Imidacloprid: 8.80%)  
109701 (Permethrin: 44.00%)  
129032 (Pyriproxyfen: 0.44%)

From: Byron T. Backus, Ph.D., Toxicologist  
Technical Review Branch  
Registration Division (7505P)

To: Linda DeLuise/Richard Gebken RM 10  
Insecticide Branch  
Registration Division (7505P)

Registrant: BAYER HEALTHCARE LLC

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129099 Imidacloprid	8.80%
109701 Permethrin	44.00%
129032 Pyriproxyfen	0.44%
<u>Other Ingredients:</u>	<u>46.76%</u>
<b>TOTAL</b>	<b>100.00%</b>

**ACTION REQUESTED:** "Spot-on label in response to Lois's letter dated 9/30/11. Please evaluate CASS data base to determine minimum weight range. Label and transmittal document enclosed."

*Lois's letter dated 9/30/11*

**BACKGROUND:** The registrant is proposing a revision of the weight and age restriction statement. According to the attachment: "The minimum weight was determined from the EPA-accepted Companion Animal Safety studies for this product." The proposed label statement is: "Do not apply to dogs weighing less than 3½ lbs." The dosage rate is 0.4 mL/application.

**COMMENTS AND RECOMMENDATIONS:**

1. According to our records, the companion animal safety study in puppies data requirement for this product was satisfied by bridging from between two studies, MRIDs 45097101 and 45563003, both using 7 week old puppies. The study in MRID 45097101 was conducted on an Imidacloprid (9.1%) + Pyriproxyfen (0.9%) formulation, which had been previously classified as acceptable (TXR 5001580, TRB memorandum dated September 8, 2000) with a 1X dosage rate of 0.4 mL/puppy. The study in MRID 45563003 was conducted on an Imidacloprid (8.84%) + Permethrin (43.73%) formulation and had been previously classified as acceptable (TXR 5002455, TRB memorandum dated June 28, 2002).
2. In the study in MRID 45097101 2.0 mL (5 X 0.4 mL) of test material was topically applied to each of 14 Group A puppies on Days 0, 7, 14 and 21. On Day -1 the mean weights  $\pm$  S.D. of Group A puppies were the following (as calculated from data on p. 28 of MRID 45097101): males:  $3.44 \pm 0.39$  lbs; females:  $3.06 \pm 0.45$  lbs; combined sexes:  $3.25 \pm 0.45$  lbs.
3. In the study in MRID 45563003 2.0 mL (5 x 0.4 mL) of test material was topically applied to each of 12 Group B puppies on Days 0, 7, 14 and 21. On Day 0 the mean weights  $\pm$  S.D. of Group B puppies were the following (calculated from data on pages 38-39 of MRID 45563003): males:  $2010 \pm 360.7$  (=  $4.43 \pm 0.80$  lbs); females:  $1645 \pm 164.9$  (=  $3.62 \pm 0.36$  lbs); combined:  $1827.5 \pm 328.4$  g (=  $4.03 \pm 0.72$  lbs).
4. Based on the Day 0 mean body weights of the puppies in the study in MRID 45563003 TRB concludes that the appropriate statement is: "Do not apply to puppies weighing less than 4 lbs."

## Discussion of Claims for registration 92334-R Evergreen Spot on for Dogs

1)

### Claim:

[Compare to K9Advantix® II for Dogs, contains same active ingredients\* (or)  
Contains same active ingredients as K9Advantix® II for Dogs\*]

\*This product is not manufactured or distributed by Bayer, the maker of K9Advantix® II.  
K9Advantix® II is a registered trademark of Bayer.]

### *Comment Julie Breeden:*

This type of comparison claim can only be made if the Active Ingredients and the % of those Active Ingredients are the same.

### *Answer Olaf Hansen:*

Julie,

this is very hard to understand and to accept for us and I hope I can persuade you that our product can be compared to K9Advantix II.

First of all, we had a pre-registration meeting with EPA on March 10, 2016, and it was agreed that our product can be compared to K9Advantix II and that we were allowed to cite all toxicological and efficacy data of Bayer.

The reason why our product is comparable to K9Advantix II is very simple. We apply the same active ingredients in the same amounts as K9Advantix II.

*Related to email 1/10/17  
All discussed at 1VB PM mtg  
1/24/17*

Table 1: Dosage comparison K9Advantix II / Evergreen II

	K9Advantix II	EVERGREEN II 92334-R
<b>Active concentration</b> (Weight/Weight)		
Permethrin	44%	35.6%
Imidacloprid	8.8%	7.12%
Pyriproxyfen	0.44%	0.36%
<b>Active concentration</b> (Weight/Volume)		
Permethrin	50%	41.67%
Imidacloprid	10%	8.34%
Pyriproxyfen	0.5%	0.42%
<b>Application volume</b>	1.0 ml / 10kg	1.2 ml / 10kg
<b>Active dosage</b>		
Permethrin	50 mg/kg	50 mg/kg
Imidacloprid	10 mg/kg	10 mg/kg
Pyriproxyfen	0.5 mg/kg	0.5 mg/kg

As you can see in table 1 with Evergreen II and K9Advantix II the identical amounts of actives are applied to the dog. That means that each of the dose tubes carry the identical amounts of actives.

The dosage for Permethrin is 50 mg/kg b.w., for Imidacloprid it is 10 mg/kg b.w., and for Pyriproxyfen the applied amount per kg body weight is 0.5 mg.

The claim says: Compare to K9Advantix® II for Dogs, contains same active ingredients\* (or) Contains same active ingredients as K9Advantix® II for Dogs\*.

Evergreen fulfills this claim as Evergreen II contains the same active ingredients. And in addition to that we even apply the identical amounts of actives on the dog.

From a veterinarian or a customer point of view it is not important which percentage a product has, it is important which dosage is applied to a dog. I hope you can agree to this. If you have the same concentration on the label (given weight/weight), it is not guaranteed that you apply the same dosage. The dosage depends on the solvent system and if the density is different from the originator, the applied dosage is different (even with the same concentration on the label).

I hope you can follow my argumentation and I hope that you will change your opinion, so we are able to use this very important claim for us. If you want to discuss this claim on the phone, I would be happy to call you.

⇒ Adjust wording per <sup>MS</sup> P11 mtg 24.7

2)

**Original Claim from the Hazards to Domestic Animals section:**

Do not use on puppies under seven weeks of age or weighing less than 4 lbs.

***Comment Julie Breeden:***

This wording excludes dogs that weigh less than 4 lbs. in general.

Rephrase to include dogs that are over seven weeks of age, but under 4 lbs. Something like this works: Do not use on dogs or puppies under seven weeks of age or weighing less than 4 lbs.

***Our answer:***

This is our proposal:

Do not use on dogs or puppies under seven weeks of age or weighing less than [4 lbs] [11 lbs] [21 lbs] [55 lbs].

3)

Several 1-800 numbers:

Julie, there will be an appropriate 1-800 number on each package. As we anticipate having a number of different supplemental distributors, each with their own 1-800 number, at this time providing only one 800 would not be correct

4)

**Original Claim:**

Side effect section:

Side effects, although rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort.

***Julie Breeden question:***

Is there a quantified definition for rare here?

***Our answer:***

We are not aware of an official definition of the term “rare”. The Bayer label states:

Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort.

So, we have used the wording from the cited label.

5)

**Claim:**

Evergreen II Spot On for Dogs is waterproof and will remain effective even after a shampoo treatment, after swimming or after exposure to rain or sunlight.

***Julie Breeden comment:***

I know it isn't on the cited label either, but consider the following questions? If I put this product on my dog 2 hours before he goes swimming, does the product remain effective? If my dog goes swimming in a lake and then receives a bath 6 hours after application, is the product still effective? Unqualified waterproof statements are under discussion... just a heads up that the topic will likely come up again in the future.

***Olaf Hansen comment:***

I know exactly what you mean, Julie. I don't know if you know that I am one of the inventors of K9Advantix II and I have always argued with my colleagues, that efficacy may decrease if a dog goes swimming or got shampooed. But I was in R&D and my former Marketing colleagues saw this differently. Nevertheless Bayer (and myself) did the clinical studies and it was shown that efficacy did not decrease in those studies.

But: We will keep this in mind and once you will inform Bayer and many other companies that sell parasiticides, we'll change this claim accordingly.

From a chemical perspective, just using water to remove the active ingredients which are lipophilic and not very water soluble from the skin and/or fur will not be very effective. Once the active ingredients spread, a dog could probably swim until his legs fall off, and the water alone will not remove the active ingredients and consequently affect the efficacy. However, if a surfactant such as those present in shampoos is used to try to remove the active ingredients, there will be more success. How successful this process will be will probably depend on many, many factors, such as the chemical nature of the surfactant, how vigorously the dog is shampooed, how long is the dog shampooed, the nature of the dogs skin and fur, how much active ingredient was present at the time of shampooing (was it shampooed 2 days after treatment or 25 days after treatment), etc., etc. There is probably no way to design one study to answer all the possible questions that can be asked. The current requirement does demonstrate that if a dog swims or is shampooed in a normal manner, the product is still effective. In actuality, the shampoo process might remove a few

percent of the active ingredients, but this is not enough to demonstrate a difference in efficacy, particularly as many products are intentionally formulated to perform greater than 30 days, such as for 35 – 42 days to ensure complete monthly control.

6)

[How to apply direction for aluminum/plastic tube container:]

**Julie Breeden question:**

Is there any kind of difference between the aluminum vs. plastic tube types that could affect any degree of CRP?

**Our answer:**

This product does not need to be packed in a Children Resistant Packaging, and is not being packaged in CRP containers .

Additionally we would like to add this below icon to the “How to Apply” section:

[Note to reviewer: A dog icon that shows the application may be added to this section “how to Apply”]



This dermal application icon should be another point to increase safety of this product.

7)

Discard empty tube as described in Storage and Disposal.

**Julie Breeden question:**

section found where?

**Answer:**

The Storage and Disposal section is right below this paragraph.



8)

Do not retreat more than once every week.

**Julie Breeden question:**

This is on the cited label, but here is a question that speaks to safety and prevention of misuse: How many times can a consumer apply the product once every week before a toxic effect is seen?... weekly for 4 consecutive weeks? up to 8 consecutive weeks?

**Our answer:**

For retreatment intervals, the general rule the Agency (Dr. Byron Backus) has used is that retreatment cannot be done earlier than one month unless the registrant has safety data to demonstrate safety at retreatment earlier than one month. Previously in many safety studies, the animals were treated once a month for multiple (usually 3) months. Particularly when there was no concern about the safety of the product, the safety studies could be shortened by retreating the animals at shorter intervals than once a month. For example, animals might be treated once a week for 3 weeks instead of once a month for 3 months; this shortens the in-life portion of the study dramatically, in addition to demonstrating safety at a shorter retreatment interval. Where these data at retreatment intervals of less than 4 weeks demonstrating safety are available, EPA granted a shorter retreatment interval.

For this product, the safety data are the same safety data used for the registration of K9Advantix. Further, K9Advantix II has been on the market for over 10 years and it is considered as a very safe product for dogs. Otherwise it wouldn't be so successful.

Our product was able to cite all toxicological data from the Originator, therefore we used of course the wording from the cited label.

9)

- [6-Way Protection] [image or icon of flea, flea eggs, tick, mosquito, biting fly, lice]
- Prevents & Kills: Biting Flies and Lice

No kills biting flies claims

Protection from flea eggs?

**Julie Breeden comment:**

The 5-way claim as noted on the cited label would be acceptable. Claims don't allow for kills biting flies. What icon would you plan to use for biting flies as opposed to the other pests where kills claims are on the label?

***Olaf Hansen comment:***

As there are 6 icons it should be possible to say 6-Way Protection. This is the truth and it should be possible to say this. The cited label says also 3-way and 5-way depending on the claims they put after this phrase, so it should be possible that we are allowed to say 6-way as long as we tell the truth. The sixth additional icon are just flea eggs, which are an official claim.

Sorry for overseeing the killing claim against Biting Flies. I have not realized that there is no killing claim. I have deleted all killing claims against biting flies.

Please find below the icons we want to use for the six-way protection claim:



! Can't tell biting fly vs. other fly  
Specifically Repels biting flies (no kill claim)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**SIMILARITY CLINIC MEMORANDUM:**

June 2, 2016

Subject: EVERGREEN II SPOT ON FOR DOGS  
EPA File Symbol: 92334-R  
DP Barcode 433530  
Action Code: R315  
PC Codes: 109701 (Permethrin: 35.6%)  
129099 (Imidacloprid: 7.12%)  
129032 (Pyriproxyfen: 0.36%)

From: Byron T. Backus, Ph.D., Toxicologist  
CITAB  
Registration Division (7505P)

*Byron T. Backus*  
*June 2, 2016*

Through: John Redden, M.S., Senior Risk Assessor  
CITAB  
Registration Division (7505P)

*JCR*

To: Meredith Fry RM 04  
Invertebrate-Vertebrate Branch 1  
Registration Division (7505P)

Applicant: EVERGREEN ANIMAL HEALTH, LLC

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
129099 Imidacloprid.....	7.12%
109701 Permethrin.....	35.60%
129032 Pyriproxyfen.....	0.36%
<u>Other Ingredients:</u> .....	<u>56.92%</u>
<b>TOTAL:</b>	<b>100.00%</b>

**BACKGROUND:** The registrant is claiming similarity to two products, EPA Reg. Nos. 11556-116 and 11556-141. EPA Reg. No. 11556-116 has a label declaration of 9.1% imidacloprid as sole active ingredient, while 11556-141 has a label declaration of 8.8% imidacloprid, 44% permethrin and 0.44% pyriproxyfen. The registrant's rationale for a claim of similarity to 11556-116 apparently is based on one or more of the inerts present in 92334-R.

According to the data matrix (dated 04/20/2016), the registrant is citing the following acute toxicity studies: MRIDs 470143-08 and 436796-01 (acute oral LD<sub>50</sub>); 470143-06 and 436796-02 (acute dermal LD<sub>50</sub>); 470143-07 and 436796-04 (eye irritation); 470143-04 and 436796-05 (dermal irritation); and 470143-03 and 436796-06 (dermal sensitization). The registrant has submitted a waiver request (MRID 498978-05) for the acute inhalation LC<sub>50</sub> requirement. In addition, the registrant is citing the following MRIDs to satisfy the 870.7200 data requirements: 470143-09; 455630-03; 450971-01; 440998-01; 436796-07; and 436796-08 and 450971-02.

#### COMMENTS AND RECOMMENDATIONS:

1. According to OPPIN Query MRIDs 470143-03, -04, -06, -07 and -08 were used to support 11556-141, while MRIDs 436796-01, -02, -04, -05 and -06 were used to support 11556-116.
2. After comparing the CSF (dated April 19, 2016) for 92334-R with the CSFs for 11556-116 and 11556-141, and taking into consideration the inerts and solvents in 92334-R, CITAB concludes that 92334-R is toxicologically similar to 11556-141.
3. The studies in MRIDs 470143-03, -04, -06, -07 and -08 have been previously reviewed (TRB memorandum dated June 6, 2007 for 11556-RUR). The following is a partial acute toxicity profile for EPA Reg. No. 11556-141, based on the results of these studies:

Acute oral toxicity	III	Acceptable	MRID 47014308
Acute dermal toxicity	IV	Acceptable	MRID 47014306
Primary eye irritation	II	Acceptable	MRID 47014307
Primary dermal irritation	III	Acceptable	MRID 47014304
Dermal sensitization	Negative	Acceptable	MRID 47014303

4. The material received includes a waiver request (MRID 498978-05: Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for Evergreen Spot on for Dogs). It is noted that the product is packaged in small quantities (0.48-4.8 mL) in sealed, single-use application tubes; the active ingredients are nonvolatile; and application does not result in respirable particles. In addition, the test article is designed to adhere to treated animals for efficacious control of the target pests.

CITAB concludes that a waiver from the requirement of an inhalation study on this formulation is appropriate, with assignment of this product to toxicity category IV by the inhalation exposure route.

5. Based on the considerations indicated above, the following is the acute toxicity profile for 92334-R:

Acute oral toxicity	III	Cited	MRID 47014308
Acute dermal toxicity	IV	Cited	MRID 47014306
Acute inhalation toxicity	IV	Waived	MRID 49897805
Primary eye irritation	II	Cited	MRID 47014307
Primary dermal irritation	III	Cited	MRID 47014304
Dermal sensitization	Negative	Cited	MRID 47014303



6. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 92334-R, as obtained from the Label Review System:

**PRODUCT ID #:** 092334-00001

**PRODUCT NAME:** EVERGREEN II SPOT ON FOR DOGS

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** WARNING

**Hazards to Humans and Domestic Animals:**

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on skin or clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, socks, shoes, and gloves.

**First Aid:**

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

7. The acute toxicity data requirements for the registration of 92334-R, Evergreen II Spot On for Dogs, have been satisfied.
8. The label specifies the following tube sizes: 0.016 fl. oz. (0.48 mL); 0.041 fl. oz. (1.2 mL); 0.101 fluid oz. (3.0 mL); and 0.162 fl. oz. (4.8 mL), which are respectively associated with the following weight treatment ranges: 4-10 lbs; 11-20 lbs; 21-55 lbs; and over 55 lbs. The registrant is citing the following MRIDs to satisfy the 870.7200 data requirements (and application rates): 470143-09; 455630-03; 450971-01; 440998-01; 436796-07; and 436796-08 and 450971-02.
9. The study in MRID 470143-09 was reviewed by TRB (June 6, 2007 memorandum for 11556-RUR). The following is from the executive summary:

*In a companion animal safety study (MRID 47014309), two groups, each containing 6 male and 6 female adult (11 ½ to 12 ½ months old) beagle dogs (Day -1 weights: males: 6.446 - 9.914 kg; females: 6.495 - 9.438 kg) were treated at a 5x fill volume/application (for dogs weighing 11-20 lbs the dose volume is 1.0 mL, or the amount that can be squeezed from an application tube; the fill volume for that tube is 1.05 mL, so each dog received 5 x 1.05 mL or 5.25 mL; likewise, dogs weighing 20-55 lbs were treated with 5x the fill volume of 2.58 mL or 12.9 mL). Dogs in the control group received an application of mineral oil, while dogs in the 5x test material group were dosed with the Imidacloprid-Permethrin-Pyriproxyfen formulation as proposed for registration. Dogs were treated on Days 0, 7, 14 and 21 (label instructions specify once-a-month dosing, so the cumulative dose of the 5x group over a 21-day period was 20x the normal use exposure).*

*All dogs survived and there was no indication of any effects on body weight or food consumption. No neurological effects, abnormalities or any other indications of toxicity were observed. Sporadically statistically significant differences in hematology and/or clinical chemistry parameters were not biologically relevant, and values were generally within the historical control ranges of the performing laboratory. Overall, there were no indications of any effects on hematology or clinical chemistry parameters.*

*This study is classified as **Acceptable** as a companion animal safety study (OPPTS 870.7200) for adult dogs, and demonstrates a greater than 5X margin of safety for the proposed use of this formulation on adult dogs.*

10. The study in MRID 470143-09 supported the following Advantix II registrations: 11556-141 (for small dogs weighing 4-10 lbs with a dosage rate of 0.014 fl. oz. or 0.4 mL); 11556-142 (for medium dogs weighing 11-20 lbs with a dosage rate of 0.034 fl. oz. or 1.0 mL); 11556-143 (large dogs weighing 21-55 lbs; with a dosage rate of 0.084 fl. oz. or 2.5 mL); 11556-144 (extra large dogs weighing >55 lbs with a dosage rate of 0.135 fl. oz. or 4.0 mL). All four products have label declarations of 8.8% Imidacloprid, 44% Permethrin, and 0.44% Pyriproxyfen. The proposed product has a label declaration of 7.12% Imidacloprid; 35.6% permethrin; and 0.36% pyriproxyfen; these are (respectively) 80.9%, 80.9% and 81.8% of the declarations on the Advantix products. Comparing the proposed dosage rates for 92334-R with those of the Advantix products (dogs weighing 4-10 lbs: 0.48 mL vs. 0.4 mL, or 1.2X; 11-20 lbs: 1.2 mL vs. 1.0 mL, or 1.2x; 21-55 lbs: 3.0 mL vs. 2.5 mL, or 1.2X; >55 lbs: 4.8 mL vs. 4.0 mL, or 1.2X) indicates they would be dosed at 97.09% of the imidacloprid and permethrin, and at 98.16% of the pyriproxyfen rates of the Advantix products.
11. The study in MRID 45563003 supported the following Advantix registrations: 11556-132, -133, -134 and -135; all with declarations of 8.8% imidacloprid and 44.0% permethrin (no pyriproxyfen). The following is from the executive summary of a TRB review for 11556-132 dated June 28, 2002:

*In a companion animal safety study (MRID 45563003) Imidacloprid (8.84% w/w) and Permethrin (43.73% w/w) Topical Solution (Lot No. A-01-048-G804-01-02-11), containing 100.8 mg of imidacloprid and 498.5 mg permethrin per mL, was dermally applied as a single 2 mL (5X the proposed use dosage rate of 0.4 mL) dose to the dorsal cervical area of each puppy in a group of 6 male and 6 female young (≤ 7 weeks old at initiation of dosage) on days 0, 7, 14 and 21. (The proposed 1X rate is 0.4 mL for dogs and puppies weighing ≤ 10 lbs; 1.0 mL for dogs weighing 11-20 lbs; 2.5 mL for dogs weighing 21-55 lbs, and 4.0 mL for dogs weighing ≥ 55 lbs.) A second*

(control) group of 6 male and 6 female dogs of the same age received an application of 1.0 ml. vehicle (formulation without active ingredients) on days 0, 7, 14 and 21.

For test group males on day 0 individual doses ranged from 931.4 mg test substance (82.3 mg Imidacloprid and 407.3 mg Permethrin)/kg to 1614 mg test substance (142.7 mg Imidacloprid and 795.6 mg Permethrin)/kg. In test group females individual doses on day 0 ranged from 1220.6 mg test substance (107.9 mg Imidacloprid and 533.7 mg Permethrin)/kg to 1581.1 mg test substance (139.8 mg Imidacloprid and 691.4 mg Permethrin)/kg. On day 28 in the treated group males individual doses ranged from 636.0 mg test substance (56.2 mg Imidacloprid and 278.1 mg Permethrin)/kg to 1108.4 mg test substance (98.0 mg Imidacloprid and 484.7 mg Permethrin)/kg. In the treated group females individual doses on day 28 ranged from 807.7 mg test substance (71.4 mg Imidacloprid and 353.2 mg Permethrin)/kg to 1301.4 mg test substance (115.0 mg Imidacloprid and 569.1 mg Permethrin)/kg.

Clinical observations were conducted hourly for 4 hr following each treatment; on other days each puppy was observed at least twice a day.

The report states that there was no evidence of adverse or irreversible clinical signs demonstrated by the puppies on the days of dosing or at other times during the study, and that the test substance and vehicle were well retained within the haircoat. However, while the report states (p. 26 of MRID 45563003) that: "Food consumption was not considered to have been influenced by compound administration (females or males) during the course of the study" mean food consumption for the 5X puppies on day 1 was considerably lower than that for their controls (food consumption data for both 5X and controls are for combined males and females); 323.75 g vs. 478.25 g. On day 8 mean food consumption for the 5X puppies was 580.25 g vs. the control value of 686.25 g. The food consumption differences on days 1 and 8 (day 1: 5X animals consumed 32.3% less food per pup than their controls; day 8: 5X puppies consumed 28.4% less food per pup than their controls) were the largest daily differences observed during this study. There was also a somewhat lower food consumption in the period from day 14 to day 16, although this was not as pronounced as those following the first two application treatments. There is no evidence that there was lower food consumption in the 5X puppies following the fourth (day 21) application treatment. It is also noted that 5X puppies recovered their appetites by the third day after each treatment.

There was a clustering of soft or mucoid red feces on day 20. In addition, red mucoid feces were noted in some of the puppies during the first four days of the study which were confirmed by fecal flotation as a mild, subclinical coccidiosis, and all puppies were treated with Tribrissen, 60 mg, sid for three days starting on day 4. Another puppy received a dose of kapectate on day 3.

There was no evidence of any other adverse effect in these puppies. Sporadically statistically significant differences between groups with respect to hematology and clinical chemistry parameters were not biologically significant (values were still within the normal range, or mean values were skewed by the value from puppy DM1102).



*It is noted that not all of these puppies treated at a 5X site-specific application rate, but that they were also given four 5X treatments in a 21-day period (as the label specifies once-a-month treatment at the 1X label, these puppies then received a cumulative of 20X the monthly dose specified on the label).*

*This study generally followed the pertinent guidelines for a companion animal safety study (OPPTS 870.7200).*

*The study is classified as Acceptable in demonstrating an adequate (approximately 5X in terms of overt symptoms) margin of safety. While treated puppies did not eat as much as their controls following on days 1 and 8 following applications of the test material on days 0 and 7, their food consumption recovered in a day or so, and there was little or no evidence of any reduction in food consumption following the third and fourth applications of the test material.*

12. In a TRB memorandum for 11556-132 dated June 17, 2013, the following was stated:

According to our records, the companion animal (7 week-old puppy) safety study data requirement for this product was satisfied by the study in MRID 45563003). The study in MRID 45563003 was conducted on an Imidacloprid (8.84%) + Permethrin (43.73%) formulation and has been classified as acceptable (TXR 5002455, TRB memorandum dated June 28, 2002).

In the study in MRID 45563003 2.0 mL (5 x 0.4 mL) of test material was topically applied to each of 12 Group B puppies on Days 0, 7, 14 and 21. On Day 0 the mean weights  $\pm$  S.D. of Group B puppies were the following (calculated from data on pages 38-39 of MRID 45563003): males:  $2010 \pm 360.7$  (=  $4.43 \pm 0.80$  lbs); females:  $1645 \pm 164.9$  (=  $3.62 \pm 0.36$  lbs); combined:  $1827.5 \pm 328.4$  g (=  $4.03 \pm 0.72$  lbs). Taking the 4 male and 4 female least weight puppies would give a mean weight of  $1697 \pm 251$  g (=  $3.74 \pm 0.55$  lb).

Based on the Day 0 mean body weights of the puppies in the study in MRID 45563003 TRB concludes that the appropriate statement is: "Do not apply to puppies weighing less than 4 lbs."

13. The study in MRID 45097101 was reviewed by TRB (September 8, 2000 memorandum for 11556-125). The following is from the executive summary:

*In a companion animal safety study (MRID 45097101), Advantage Plus<sup>h</sup> for Dogs (Active Ingredients: 9.1% Imidacloprid w/w; 0.9% Pyriproxyfen w/w) was applied topically at a dose of 2.0 mL/puppy (5X the label specified dose of 0.4 mL puppy for puppies  $\leq 10$  lbs) to a group of 7 male and 7 female beagle puppies, seven weeks of age at the time of first treatment. Individual weights of the puppies in the treatment group ranged from 2.54 to 4.01 lbs (1.15-1.82 kg) on day -1. Controls (7M, 7F; weight range: 2.49-5.03 lbs; 1.13-2.29 kg) were dosed with the vehicle alone at a dose of 2.0 mL/puppy (5.6X the volume of the vehicle present in the specified dose). Both groups were treated on study days 0, 7, 14, and 21. The recommended label dose is once a month. However, the labeling for these products includes the statement: "If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly."*



*There were no deaths during the study. Following all treatments, a rough hair coat condition at the application site was noted on 3-14 puppies of both groups, and white powder was occasionally noted at the application sites; however, there were no signs of irritation. One puppy from the test substance group was found to have ocular discharge and "crusty patches" on its ventral abdomen, by the lip and under each eye on study day 36. The puppies completed treatment for coccidiosis on study day -8. During the remainder of acclimation, in the test substance group there were two observations of loose feces with mucous and five observations of diarrhea, with or without mucous or red colored mucous, exhibited by four animals. In the vehicle control group, there were two observations of loose feces with mucous, exhibited by two animals.*

*The guideline states that animals should be free from infectious diseases which could complicate the interpretation of study results. It is concluded that, while marginal (in the vehicle control group there were 7 observations of diarrhea - one with blood - exhibited by 5 animals, and in the test substance group there were 2 observations of diarrhea in 2 separate females, 4 observations of loose feces with mucous made on a single female on day 14 post-dosing, and one observation of red mucous, exhibited by a male on day 22) these incidences are low enough that we can consider the study not to be compromised. In addition, the puppies had adequate weight gains during the treatment period. Overall, it appears that the puppies were infected when they arrived at the laboratory but were adequately treated. In addition, they may have been under some stress. The Agency recognizes the difficulties inherent in conducting this type of study under these circumstances, particularly when treatment has to be initiated when the animals are no more than seven weeks old and there are severe scheduling constraints.*

*It is also noted that this formulation is similar to those of a number of existing registered products, except for the addition of 0.9% pyriproxyfen for efficacy against flea eggs. Pyriproxyfen is known to have extremely low toxicity (both acute and chronic) to mammalian species. In addition, the proposed products which this study is supporting contain 0.46% pyriproxyfen, rather than 0.9%.*

*Despite the fact that the puppies may not have been entirely free of infection, and despite some deficiencies in the reporting of the data, the study is classified as **Acceptable** as a companion animal safety study (OPPTS 870.7200) in puppies. The lack of any indications of a consistent toxicological response following exposures (a total of 4) to 5X label-specified use applications of the test material indicates that an adequate safety margin exists for this formulation and its proposed use on puppies 7 weeks of age and older.*

14. The study in MRID 44099801 was reviewed by HED (TXR 0012322, sign-off date 9/24/97). The following is from the executive summary:

*In a domestic animal safety study (MRID # 44099801), six 7 week-old puppies/sex were treated with Advantage™ (9.1% imidacloprid) at 5X the recommended use rate (2.0 ml if < 10 lbs; 5.0 ml if > 10 lbs) at weekly intervals for eight treatments. Six puppies/sex were treated with the vehicle control at the recommended use rate (0.4 ml if < 10 lbs; 1.0 ml if > 10 lbs) at weekly intervals for eight treatments. There was no evidence of treatment-related toxicity in clinical signs or clinical pathology parameters. All animals gained weight during the study. It was demonstrated that 7 week-*

*old puppies can tolerate up to 5X the recommended use rate.*

*The study is considered acceptable and satisfies the draft guideline requirements (81-6) for a domestic animal safety study.*

15. The study in MRID 43679607 was reviewed in HED (TXR 0011821, 03/05/96) with the following summary:

*Nine adult dogs of mixed breed (3 males, 6 females, one male and two females/group) were dermally exposed to Imidacloprid, 10% Spot-On. Dose levels were 50 mg/kg/day x 1 day, and 50/mg/kg/day x 3 days. Controls received placebo (formulation less active ingredient) at 50/mg/kg/day x 3 days. Animals then were observed for 14 days.*

*No major treatment related dermal, clinical signs, body weight effects or clinical chemistry changes were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg without significant reactions.*

*This acute dermal study is classified as Acceptable when combined with another study, and satisfies the requirements for a domestic animal study in the dog, 18 lb (8 kg) body weight and above. The number of animals/group is too small and not in keeping with general study practice. However, when data are combined with the companion study in the dog (MRID 43679608), the information is considered useful.*

16. The study in MRID 43679608 was reviewed in HED (TXR 0011821, 03/05/96) with the following summary:

*18 adult dogs of various breeds (3 males and 3 females / group) were dermally exposed to Imidacloprid, 10% Spot-On formulation at seven-day intervals for a total of eight treatments. Dose levels were 10 or 50 mg/kg. Controls received placebo (formulation less active ingredient) at 50/mg/kg.*

*No major treatment related dermal, clinical signs, body weight effects or clinical chemistry/hematology were observed. Necropsy was not done due to lack of toxicosis. The study demonstrates that adult dogs can tolerate up to 50 mg/kg of the active ingredient without significant reactions. Inadequate testing was done in dogs less than four months old.*

*This repeated dose dermal study is classified as Acceptable and satisfies the requirements for a General Safety Evaluation for Topical Use (86-1) in the dog.*

17. The study in MRID 45097102 was reviewed by TRB (September 8, 2000 memorandum for 11556-125). The following is from the executive summary:

*In a companion animal safety study (MRID 45097102) with adult beagles (ages ranging from 1 year and 3 months to 6 years), Advantage Plus® for Dogs (Active Ingredients: 9.1% Imidacloprid w/w; 0.9% Pyriproxyfen w/w) was applied topically at dose volumes of 5.0 mL for dogs weighing 11-20.4 lbs and 12.5 mL for dogs weighing 20.5-55 lbs. (five times the*

recommended dose, groups of 6 male and 6 female dogs. All dogs were consistently dosed with 12.5 mL of the formulation/application, and four were consistently dosed with 5 mL/application. Controls were dosed with the vehicle at dose volumes of 5.0 mL for dogs weighing 11-20.4 lbs and 12.5 mL for dogs weighing 20.5-55 lbs. (5.6 times the volume of the vehicle present in the recommended dose). Five dogs were consistently treated with 12.5 mL vehicle/application, five were consistently dosed with 5 mL/application, and two dogs received 12.5 mL/application for the first, second and fourth applications, and 5.0 mL/application for the third application. Dogs were treated on study days 0, 7, 14, and 21.

There were no deaths during the study. The dogs received no concomitant medication or therapy during the treatment period. The most prominent clinical sign was a rough appearance of the hair coats on dogs from both groups following treatment and lasting for up to 36 hours; however, there were no signs of irritation at the application sites. Several dogs from both groups, "jumped excessively due to excitement" on study day 21. The study report did not indicate which dogs. Three dogs (two from the test substance group and one from the vehicle control group) also exhibited sore footpads on that date. These findings for day 21 were not noted at any other time during the study. There were no treatment related effects on body weights, food consumption, or clinical pathology parameters.

It is also noted that the proposed products (containing approximately 9% Imidacloprid, but only 0.46% pyriproxyfen, rather than the 0.9% in the formulation as tested) are similar to existing registered products containing 9% Imidacloprid as sole active. Pyriproxyfen is known to have a low toxicity to mammalian species.

The study is classified as **Acceptable/Guideline** as a companion animal safety study (OPPTS 870.7200) in dogs. The lack of any consistent indications of a toxicological response following exposures (a total of 4) to 5X label-specified use applications of the test material indicates that an adequate safety margin exists for this formulation and its proposed use on adult dogs.

18. The 7-week minimum age puppy claim and the minimum weight claim of 4 lbs are largely supported by the study in MRID 45563003. However, this study was conducted on a formulation containing 8.84% imidacloprid and 43.73% permethrin as active ingredients (no pyriproxyfen). In order to completely satisfy the 870.7200 data requirements for the use on puppies and dogs, the registrant should also cite the following study: MRID 42178309 [Chapman, E. (1991) S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Similar Technical Grade): Lab Project Number: 91/0776. Unpublished study prepared by Life Science Research Ltd. 320 p.]. This study demonstrates that pyriproxyfen has a very low toxicity to mammalian species. With this additional study citation, the 870.7200 data requirements for the registration of 92334-R will have been satisfied.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

~~Contains Confidential Business Information~~

**DP BARCODE No.:** 434007; **FILE SYMBOL No.:** 92334-R; **PRODUCT NAME:** Evergreen II Spot On for Dogs; **DECISION No.:** 516525; **PC Code(s):** 109701, 129032, 129099; **ACTION CODE:** R315; **FOOD Use:** NO

**DATE OUT:** December 12, 2016

**SUBJECT:** End Use Product Chemistry Review – *Evergreen II Spot On for Dogs*  
-Three Active Ingredients; Substantial Similarity ("Me-Too") Claim Registration

**FROM:** Maria I. Rodriguez, Chemist  
Product Chemistry Reviewer  
CITAB/RD (7505P)

*Maria I. Rodriguez  
December 12, 2016*

**THROUGH:** Shyam Mathur, Ph. D.  
Product Chemistry Team Leader  
CITAB/RD (7505P)

*SMathur 12.13.16*

**TO:** Julie Breeden/Kable Davis, RM #4  
IV #1/RD (7505P)

**INTRODUCTION:**

The CITAB (Chemistry) has been asked to determine the acceptability of supporting Product Chemistry data submitted with this application.

*Registrant:* Evergreen Animal Health, LLC

*Application Date:* April 21, 2016

*Proposed Product:* Intended to be used at the nominal concentrations of 35.60% permethrin, 7.12% imidacloprid, and 0.36% pyriproxyfen as a spot on treatment to control fleas, ticks, mosquitos, biting flies, and lice on dogs as listed on the proposed label

*Supporting Data:* Basic CSF (dated 04-19-2016), Data Matrix (dated 04-20-2016), Proposed label, Studies with MRID Nos 498978-01, -02, -03, & -04

*Claim:* Substantially Similar to EPA Reg No 11556-116 (*Advantage 9 Topical Solution*) and EPA Reg No 11556-141 (*K9 Advantix II Small Dog*)

*45/90-Day Completeness Screen:* 06-14-2016 (SMathur); NO Deficiencies Listed

DP BARCODE No.: 434007; FILE SYMBOL No.: 92334-R; PRODUCT NAME: Evergreen II Spot On for Dogs; DECISION No.: 516525; PC Code(s): 109701, 129032, 129099; ACTION CODE: R315; FOOD Use: NO

**SUMMARY OF FINDINGS:**

1. Name(s) of Active Ingredient(s): 35.60% permethrin, 7.12% imidacloprid, and 0.36% pyriproxyfen
2. Has the registrant claimed substantial similarity to a registered product? ☒ Yes; ☐ No
  - EPA Reg No 11556-116 (*Advantage 9 Topical Solution*)
    - Contains imidacloprid, 9.1%
  - EPA Reg No 11556-141 (*K9 Advantix II Small Dog*)
    - Contains 44.00% permethrin, 8.80% imidacloprid, and 0.44% pyriproxyfen
3. All of the source materials of the active ingredients are derived from registered sources: ☒ Yes; ☐ No
4. All inert ingredients have been screened by CITAB (Inerts) and found to be approved for the proposed labeled use(s): ☒ Yes; ☐ No
  - Inerts approved for non-food (EFertich, 05-11-2016)
5. Confidential Statement(s) of Formula (CSFs):
  - ☒ Proposed Basic CSF: Dated: 04-19-2016
6. Product label:
  - a. Ingredient statement: Nominal concentration (NC) of AIs listed on CSF concur with product label (PR Notice 91-2): ☒ Yes; ☐ No
    - Is the sub statement in compliance with PR Notice 97-6 (inert ingredients vs other ingredients)? ☒ Yes; ☐ No
    - Metallic equivalent: ☐ Yes; ☐ No; ☒ NA
    - Soluble arsenic: ☐ Yes; ☐ No; ☒ NA
    - Isomeric ratios: ☐ Yes; ☐ No; ☒ NA
    - Acid Equivalent: ☐ Yes; ☐ No; ☒ NA
  - b. Health related sub statements: Product contains?
    - Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA
    - Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA
    - Sodium nitrate/Sodium Nitrite: ☐ Yes; ☐ No; ☒ NA
  - c. Physical-chemical hazard statement: Product label requires a statement *per* 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown? ☐ Yes; ☒ No
    - Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)? ☐ Yes; ☐ No; ☒ NA
  - d. Label requires an additional Storage and Disposal statement: ☐ Yes; ☒ No

DP BARCODE No.: 434007; FILE SYMBOL No.: 92334-R; PRODUCT NAME: Evergreen II Spot On for Dogs; DECISION No.: 516525; PC Code(s): 109701, 129032, 129099; ACTION CODE: R315; FOOD Use: NO

7. Group A: Product Chemistry Data – Product Identity, Composition, and Analysis

Guideline Number	Study Title		Data Submitted		CITAB's Assessment of CHEMISTRY Data	MRID Number Cited
			Yes	No		
830.1550	Product Identity & Composition		X		A	498978-01
830.1600	Description of materials used to produce the product		X		A	498978-01 Product Labels and/or MSDs Provided
830.1620	Description of the production process		X		A	498978-01
830.1650	Description of formulation process		X		A	498978-01
830.1670	Discussion on the formation of impurities		X		A	498978-01
830.1700	Preliminary analysis		----	----	NA	NA
830.1750	Certified limits (158.350)	Standard certified limits	X		A	498978-01
		Proposed Limits				Basic CSF 04-19-2016
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	498978-02 HPLC - UV Validated

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable;  
I = In Progress; U = Upgradeable

DP BARCODE No.: 434007; FILE SYMBOL No.: 92334-R; PRODUCT NAME: Evergreen II Spot On for Dogs; DECISION No.: 516525; PC Code(s): 109701, 129032, 129099; ACTION CODE: R315; FOOD Use: NO

8. Group B: Product Chemistry Data – Physical and Chemical Characteristics

Guideline Number	Study Title	Value or Qualitative Description	CITAB's Assessment of CHEMISTRY Data	MRID Number Cited
830.6302	Color	Clear, pale yellow	A	498978-03
830.6303	Physical State	Liquid	A	498978-03
830.6304	Odor	Typical of organic solvents	A	498978-03
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	NA; Not expected to contact metals or metal ions	NA	NA 498978-03
830.6314	Oxidation/reduction	NA; not expected to be oxidized or reduced based on the chemical structures	NA	NA 498978-03
830.6315	Flammability	NA; Not flammable (Based on components' flashpoints)	NA	NA 498978-03
830.6316	Explosibility	NA; Not explosive (Based on chemical structures)	NA	NA 498978-03
830.6317	Storage stability	To be conducted	G	G Data Matrix 498978-03
830.6319	Miscibility	NA; Not to be mixed with petroleum solvents	NA	NA Data Matrix 498978-03
830.6320	Corrosion characteristics	To be conducted	A	G Data Matrix 498978-03
830.6321	Dielectric breakdown voltage	NA; Not to be used around electrical equipment	NA	NA Data Matrix 498978-03
830.7000	pH	NA; does not have measurable hydrogen ion concentration	NA	498978-03 498978-04
830.7100	Viscosity	16 mPa @ 20 °C	A	498978-03
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	1.171 g/mL @ 20°C	A	498978-03
830.7520	Particle Size	NA; not fibrous	NA	498978-03

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable;  
I = In Progress; U = Upgradeable

DP BARCODE No.: 434007; FILE SYMBOL No.: 92334-R; PRODUCT NAME: Evergreen II Spot On for Dogs; DECISION No.: 516525; PC Code(s): 109701, 129032, 129099; ACTION CODE: R315; FOOD Use: NO

### C. CONCLUSIONS:

CITAB has reviewed the Product Chemistry data submitted and has concluded that:

#### A. Substantial Similarity to the Cited Product from Product Chemistry View Point

☐ Similar to .....

☒ Not similar to cited products

-Cited EPA Reg No 11556-116 (*Advantage 9 Topical Solution*)

-Contains imidacloprid, 9.1%

-This cited product contains only one of the active ingredients in common with the proposed product. Therefore, the products are not substantially similar.

-Cited EPA Reg No 11556-141 (*K9 Advantix II Small Dog*)

-Contains 44.00% permethrin, 8.80% imidacloprid, & 0.44% pyriproxyfen

-This cited product contains the same three active ingredients in common with the proposed product. The nominal concentrations are not similar. Therefore, the products are not substantially similar.

☐ Identical to the cited product in chemical composition

☐ Not identical

☐ Not applicable

#### B. Confidential Statement(s) of Formula

Basic CSF (dated 04-19-2016)

☒ Acceptable

☐ Not Acceptable

☐ Not Applicable

#### C. Group A Product Chemistry Data

☒ Acceptable

☐ Not acceptable

☐ Acceptable with the exception of Guideline(s): (*provide Guideline No & explain*)

☐ Not required

☐ Data cited

#### D. Group B Product Chemistry Data

☐ Acceptable

☐ Not acceptable

☒ Acceptable with the exception of Guideline(s): 830.6317 & 830.6320

-Data on "Storage Stability" & "Corrosion Characteristics" must be conducted and submitted to the Agency for review and acceptance.

☐ Not required

☐ Data cited

#### E. Product Label/Draft Label

Recommendations – Yes ☐; No ☒





Sen



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D434007; **FILE SYMBOL No.:** 92334-R (screen); **PRODUCT NAME:** Evergreen II Spot On for Dogs; **DECISION No.:** 516625; **PC Code(s):** 109701, 129032, 129099; **ACTION CODE:** R315; **FOOD Use:** No

**DATE OUT:** June 14, 2016

**SUBJECT:** 45/90 day screen results for end use product "Evergreen II Spot On for Dogs"

**FROM:** Shyam Mathur,  
Chemistry Team Leader  
CITAB / RD (7505P)

SRM

**TO:** Julie Breeden / Meredith Fry, RM 04  
I-V Branch 1 / RD (7505P)

**Company Name:** Evergreen Animal Health, LLC  
**Active Ingredient(s):** Permethrin (35.60%), Imidacloprid (7.12%), Pyriproxyfen (0.36%)  
**MRID No(s):** 49897801 to 49897804

**Deficiencies:** No

(If there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

**CONCLUSION:**

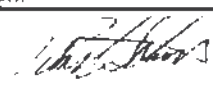
**Group A:** All required data submitted

**Group B:** All required data submitted

**CSF:** Proposed Basic CSF (dated 04-19-2016)

**Product label:** Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report the corrected deficiencies in response to 10 day letter. The corrected information will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

<b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1 Company/Product Number 92334-NEW		2 EPA Product Manager Meridith M Fry PhD	
4 Company/Product (Name) Evergreen Animal Health, LLC Evergreen II Spot On for Dogs		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5 Name and Address of Applicant (Include ZIP Code)  Evergreen Animal Health, LLC 22655 Centennial Road Gretna, Nebraska 68028  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review</b> In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 11556-141  Product Name <u>K9 Advantix II</u>	
<b>Section II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated XX-XX-XX <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below.	
Explanation Use additional page(s) if necessary (For section I and Section II.) Evergreen Animal Health, LLC is submitting a new product registration application for Evergreen II Spot On for Dogs. Evergreen Animal Health, LLC requests that the Agency review the end-use product registration as a 9 month PRIA timeframe under R315.			
<b>Section III</b>			
1 Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No  <b>*Certification must be submitted</b>	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  If "Yes" Unit Packaging wgt.      No. per Container 0.016 fl oz (0.48 mL)      1, 3, 4, 5, 6, 8, 0.041 fl oz (1.2 mL)      10, 12 tubes 0.101 fl oz (3.0 mL) 0.162 fl oz (4.8 mL)	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  If "Yes" Package wgt.      No. per Container _____ _____	2 Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
3 Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4 Size(s) Retail Container various (see above)	
		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6 Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Other <u>Printed box</u> <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
<b>Section IV</b>			
1 Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name  Robert Scharf		Title Managing Director Telephone No. (Include Area Code) (402) 215-5502	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <b>(Stamped)</b>
2 Signature BY 		3. Title Managing Director	
4 Typed Name. Robert Scharf		5. Date April 20, 2016	





United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address  Evergreen Animal Health, LLC 22655 Centennial Road Gretna, Nebraska 68028	EPA File Symbol/Registration Number <b>92334-NEW</b>
	Product Name <b>Evergreen II Spot On for Dogs</b>
	Date of Confidential Statement of Formula (EPA Form 8570-4) <b>04/19/2016</b>

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s)

**Permethrin**  
**Imidacloprid**  
**Pyriproxyfen**

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3)

(3) Indicate by checking (A) or (B) below which paragraph applies

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption:

Source		
Active Ingredient	Product Name	Registration Number
Imidacloprid		
Pyriproxyfen		
Pyriproxyfen		
Permethrin		
Signature 	Name and Title <b>Robert Scharf, Managing Director</b>	Date <b>04/19/2016</b>





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**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Evergreen Animal Health, LLC, 22655 Centennial Road, Gretna, Nebraska 68028	EPA Registration Number/File Symbol 92334-NEW
Active ingredient(s) and/or representative test compound(s) Permethrin; Imidacloprid; Pyriproxyfen	Date April 20, 2016
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood	Product Name Evergreen II Spot On for Dogs

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product, and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter, (b) I have obtained the permission of the original data submitter to use the study in support of this application, (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature, or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA, and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

April 20, 2016

Typed or Printed Name and Title

Robert Scharf, Managing Director

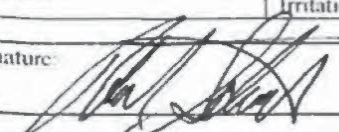




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**DATA MATRIX**

Date: April 20, 2016		EPA Reg No./File Symbol: 92334-NEW		Page 1 of 4	
Applicant's/Registrant's Name & Address Evergreen Animal Health, LLC 22655 Centennial Road Gretna, Nebraska 68028		Product: Evergreen II Spot On for Dogs			
Ingredients: Imidacloprid, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Chemistry</b>					
830.1550, 830.1620, 830.1650, 830.1670, 830.1700, 830.1750	Group A Product Chemistry For Evergreen II Spot On for Dogs	49897801	Evergreen Animal Health, LLC	OWN	
830.1800	Analytical Method for Evergreen II Spot On for Dogs	49897802	Evergreen Animal Health, LLC	OWN	
830.6302, 830.6303, 830.6304, 830.6315, 830.6316, 830.6317, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300	Summary of Group B Product Chemistry and Waivers for Evergreen Animal Health's Evergreen II Spot On for Dogs	49897803	Evergreen Animal Health, LLC	OWN	
830.6313, 830.6314, 830.1600, 830.6319, 830.6321, 830.7000, 830.7520	Physical and Chemical Characteristics: Color, Physical State, Odor, Viscosity, and Density for Evergreen II Spot On for Dogs	49897804	Evergreen Animal Health, LLC	OWN	
830.6317, 830.6320	Storage stability and corrosion characteristics	To be conducted	Evergreen Animal Health, LLC	OWN	
<b>Acute Toxicity</b>					
870.1100	Durando, J. (2005) Imidacloprid/Permethrin/Pyriproxyfen: Acute Oral Toxicity Up and Down Procedure in Rats	47014308	Bayer Healthcare LLC	PAY	
870.1100	Warren, D. (1995) Acute Oral Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats	43679601	Bayer Healthcare LLC	OLD	
870.1200	Moore, G. (2006) Imidacloprid/Permethrin/Pyriproxyfen: Acute Dermal Toxicity Study in Rats - Limit Test	47014306	Bayer Healthcare LLC	PAY	
870.1200	Warren, D. (1995) Acute Dermal Toxicity Study with Imidacloprid (Bay T-7391) 10% Pour On in Rats	43679602	Bayer Healthcare LLC	OLD	
870.1300	Waiver Request of Requirement for Further Testing for Acute Inhalation Toxicity for Evergreen II Spot On for Dogs	49897805	Evergreen Animal Health, LLC	OWN	
870.2400	Durando, J. (2006) Imidacloprid/Permethrin/Pyriproxyfen: Primary Eye Irritation Study in Rabbits	47014307	Bayer Healthcare LLC	PAY	
870.2400	Warren, D. (1995) Primary Eye Irritation Study with Imidacloprid (Bay T-7391) 10% Pour On in Rabbits	43679604	Bayer Healthcare LLC	OLD	
870.2500	Moore, G. (2006) Imidacloprid/Permethrin/Pyriproxyfen: Primary Skin Irritation Study in Rabbits	47014304	Bayer Healthcare LLC	PAY	
Signature: 		Name and Title Robert Scharf, Managing Director		Date 04/20/2016	





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 1070-0660

401 M Street, S.W.  
WASHINGTON, D.C. 20460

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## DATA MATRIX

Date: April 20, 2016	EPA Reg No./File Symbol: 92334-NEW	Page 2 of 4
<b>Applicant's/Registrant's Name &amp; Address</b> Evergreen Animal Health, LLC 22655 Centennial Road Gretna, Nebraska 68028	<b>Product:</b> Evergreen II Spot On for Dogs	

**Ingredients:** Imidacloprid, Permethrin, Pyriproxyfen

Guideline Reference No.	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500	Warren, D. (1995) Primary Dermal Irritation Study with Imidacloprid (Bay 1-7391) 10% Pour On in Rabbits	43679605	Bayer Healthcare LLC	OLD	
870.2600	Moore, G. (2006) Imidacloprid/Permethrin/Pyriproxyfen: Dermal Sensitization Study in Guinea Pigs (Buchler Method)	47014303	Bayer Healthcare LLC	PAY	
870.2600	Moore, G. (2006) Imidacloprid/Permethrin/Pyriproxyfen: Acute Dermal Toxicity Study in Rats - Limit Test	43679606	Bayer Healthcare LLC	OLD	
870.7200	<b>Companion Animal Safety</b>				
870.7200	Dandekar, D.; Schofield, J. (2006) Evaluation of the General Safety of Imidacloprid/Permethrin/Pyriproxyfen Spot-On Formulation in Adult Beagle Dogs	47014309	Bayer Healthcare LLC	PAY	Adult dogs
870.7200	Jones, R. (2001) Evaluation of the General Safety of 8.8% Imidacloprid with 44.0% Permethrin Formulation in the Target Species, 7-Week Old Puppies	45563003	Bayer Healthcare LLC (K9 Advantix)	PAY	Puppies
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Seven Week Old Puppies	45097101	Bayer Healthcare LLC (Advantage PPF)	OLD	Puppies
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Advantage) Spot-On on Puppies: Lab Project Number: TR-96D-003; 74730; 10332. Unpublished study prepared by Bayer Corp. 47 p.	44099801	Bayer Healthcare LLC (Advantage)	OLD	Puppies
870.7200	Acute Toxicity Evaluation for Dermal Treatment of Dogs with Imidacloprid (Bay 1 7391) Spot-on: Lab Project Number: 74580; TR-94D-010. Unpublished study prepared by Miles Inc. 19 p.	43679607	Bayer Healthcare LLC (Advantage)	OLD	Adult dog
870.7200	General Safety Evaluation for Topical Use of Imidacloprid (Bay 1 7391) Spot-On On Dogs: Lab Project Number: 74590; TR-95D-005. Unpublished study prepared by Bayer Corp. 40 p.	43679608	Bayer Healthcare LLC (Advantage)	OLD	Adult dog
870.7200	Evaluation of the General Safety of 9.1% Imidacloprid with 0.9% Pyriproxyfen Spot On Formulation in the Target Species, Adult Dogs	45097102	Bayer Healthcare LLC (Advantage PPF)	OLD	Adult dog
<b>Pyriproxyfen Generic Data for Companion Animal Use</b>					
	Evaluation of the Toxicology and Potential Health Risks Associated with Indoor, Nonfood Uses of Sumilarv; J. Driver, S. Oonithan, O. Paynter, et al. (1991) Unpublished study prepared by Technology Services Group, Inc. 71 p.	42182701	McLaughlin Gormley King Company	OLD	PPF

Signature:

Name and Title  
Robert Scharf, Managing DirectorDate  
04/20/2016





# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

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## DATA MATRIX

Date: April 20, 2016		EPA Reg No./File Symbol: 92334-NEW		Page 3 of 4	
<b>Applicant's/Registrant's Name &amp; Address</b> Evergreen Animal Health, LLC 22655 Centennial Road Gretna, Nebraska 68028		<b>Product:</b> Evergreen II Spot On for Dogs			
<b>Ingredients:</b> Imidacloprid, Permethrin, Pyriproxyfen					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	S31183: Toxicity Study by Oral (Capsule) Administration to Beagle Dogs for 52 Weeks (Sumilarv Technical Grade): Lab Project Number: 91/0776. Unpublished study prepared by Life Science Research Ltd. 320 p.	42178309	McLaughlin Gormley King Company	OLD	PPF
<b>810.3300</b>	<b>Efficacy</b>				
810.3300	Comparative Evaluation of How Quickly Advantage and Frontline (Fipronil) Top Spot Kill Fleas on Dogs: (Final Report)	44256901	Bayer Healthcare LLC (Advantage)	OLD	Speed of kill
810.3300	Imidacloprid Topical Formulation: Larvicidal Effect Against Ctenocephalides felis in the Surroundings of Treated Dogs	44256902	Bayer Healthcare LLC (Advantage)	OLD	Flea larvae
810.3300	Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of Advantage for Flea Control on Dogs	44256903	Bayer Healthcare LLC (Advantage)	OLD	Shampoo
810.3300	Cunningham, J. (2001) Efficacy of Topically Applied Imidacloprid and Permethrin Against Flea (Ctenocephalides felis) and Tick (Rhipicephalus sanguineus) Infestations on Dogs	45563011	Bayer Healthcare LLC (Advantix)	PAY	Brown dog tick
810.3300	Young, D. (2001) Final Report: Efficacy of Topically Applied Imidacloprid + Permethrin Against Flea (Ctenocephalides felis) and Tick (Amblyomma americanum) Infestations on Dogs	45573501	Bayer Healthcare LLC (Advantix)	PAY	Lone star tick
810.3300	Fourie, L. (2004) Assessment of the Efficacy of an Imidacloprid (10%) / Permethrin (50%) Spot-On against Stomoxys calcitrans on Dogs	46978901	Bayer Healthcare LLC	PAY	Biting flies
810.3300	Fourie, L.; Stanneck, D. (2005) Assessment of the Efficacy of an Imidacloprid 10% / Permethrin 50% Spot-On against Stomoxys calcitrans on Dogs	46978902	Bayer Healthcare LLC	PAY	Biting flies
810.3300	Cunningham, J.; Everett, R. (2002) Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of K9 Advantix for Flea and Tick Control on Dogs	47109101	Bayer HealthCare LLC	PAY	Waterproof

Signature:

Name and Title  
Robert Scharf, Managing Director

Date  
04/20/2016





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: April 20, 2016	EPA Reg No./File Symbol 92334-NEW	Page 4 of 4
<b>Applicant's/Registrant's Name &amp; Address</b> Evergreen Animal Health, LLC 22655 Centennial Road Gretna, Nebraska 68028	<b>Product:</b> Evergreen II Spot On for Dogs	

**Ingredients:** Imidacloprid, Permethrin, Pyriproxyfen

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.3300	Cunningham, J.; Everett, R.; Arther, R.; et al. (2002) Addendum I to: Evaluation of the Effects of Shampooing or Water Immersion on the Initial and Residual Efficacy of K9 Advantix for Flea and Tick Control on Dogs (Protocol and Raw Data)	47298201	Bayer HealthCare LLC	PAY	Waterproof
810.3300	Pennington, R.; Cruthers, L. (1994) Study Report for the Efficacy Evaluation of ECTO Flea and Tick Insecticide with IGR for Fleas, Ticks, and Mosquitoes	43396409	Ecto Development Corporation	OLD	Permethrin
810.3300	Pennington, R.; Cunningham, J. (1994) Study Report for the Efficacy Evaluation of ECTO Flea and Tick Insecticide with IGR for Fleas and Ticks	43396410	Ecto Development Corporation	OLD	Permethrin
810.3300	Nylar 50 (percent) Concentrate: Product Performance/Efficacy Reports. Unpublished study prepared by McLaughlin Gormley King, 79 p.	45086801	McLaughlin Gormley King Company	OLD	PPE
810.3300	Cunningham, J. (1995) Efficacy Evaluation of Bay t 7391 (Imidacloprid) 10% Solution Applied Dermal for Control of Fleas on Dogs	43679609	Bayer Healthcare LLC (Advantage)	OLD	Fleas
810.3300	Cunningham, J.; Everett, R. (1994) Efficacy Confirmation of NTN 33893 (Imidacloprid) Solution Applied Dermal for Control of Fleas on Dogs	43679610	Bayer Healthcare LLC (Advantage)	OLD	Fleas
810.3300	Doyle, J.; Egan, T. (2006) A Controlled Randomised Study to Evaluate the Efficacy of Advantage Against a Natural Infestation of Dog Lice (Trichodectes canis) Following a Single Topical Administration to Adult Mixed Breed Dogs	47190401	Bayer Healthcare LLC (Advantage)	PAY	Lice

Signature:

Name and Title  
Robert Scharf, Managing Director

Date  
04/20/2016

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 4-21-16

Experts In-Processing Signature: B.B. Date 4-25-16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>92334-R</u>		EPA Receipt Date: <u>4-21-16</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X



9	If applicable for conventional applications, <u>reduced risk rationale</u>			
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			
<p><b>Comments:</b></p> <p>Documentation <u>Pass</u> or Fail  - verification needs letter to pay checked  - Submitter contacted SLS  Submitter has sent letter to pay letter to the study owners, accepted this has been requested  All Required forms complete</p> <p>Inserts: <u>Pass</u> or Fail  - Inserts Approved for Non-Food Use</p> <p>iRIS 103: <u>Pass</u> or Fail  - MRLD 498973</p> <p>Overall <u>Pass</u> or Fail</p> <p>SV stuff</p>				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 25, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-516525  
EPA File Symbol or Registration Number: 92334-R  
Product Name: Evergreen II Spot On for Dogs  
EPA Receipt Date: 21-Apr-2016  
EPA Company Number: 92334  
Company Name: EVERGREEN ANIMAL HEALTH, LLC

ROBERT SCHARF  
EVERGREEN ANIMAL HEALTH, LLC  
22655 CENTENNIAL RD  
GRETNA, NE 68028-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY::PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "W. J. [unclear]".

Front End Processing Staff  
Information Technology & Resources Management Division

{985095G~

-----Original Message-----

From: [notification@pay.gov](mailto:notification@pay.gov) [mailto:[notification@pay.gov](mailto:notification@pay.gov)]

Sent: Tuesday, April 19, 2016 12:13 PM

To: [bob@scharf1.com](mailto:bob@scharf1.com)

Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25R51M9K

Agency Tracking ID: 74999501522

Transaction Type: Sale

Transaction Date: 04/19/2016 01:13:14 PM EDT

Account Holder Name: robert scharf

Transaction Amount: \$8,820.00

Card Type: Visa

Card Number: \*\*\*\*\*3905

Registration Number:

Company Name: Evergreen Animal Health

Company Number: 92334

Action Code: R315

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

DOCUMENTUM



